IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804 Case No. 17-md-2804
This document relates to:	Judge Dan Aaron Polster

The County of Cuyahoga v. Purdue Pharma, L.P., et al.
Case No. 17-OP-45005

City of Cleveland, Ohio vs. Purdue Pharma, L.P., et al.
Case No. 18-OP-45132

The County of Summit, Ohio, et al. v. Purdue Pharma, L.P., et al.
Case No. 18-OP-45090

Videotaped 30(b)(6) Deposition of the Drug Enforcement Administration through the testimony of Stacy Harper-Avilla

Washington, D.C.
April 11, 2019
9:16 a.m.

Reported by: Bonnie L. Russo
Job No. 3282688

Videotaped 30(b)(6) Deposition of Drug Enforcement Administration through the testimony of Stacy Harper-Avilla held at:

Arnold & Porter, LLP
601 Massachusetts Avenue, N.W.
Washington, D.C.

Pursuant to Notice, when were present on behalf of the respective parties:

APPEARANCES:
On behalf of the U S Department of Justice and the Witness:
ROBERT E CHANDLER, ESQ
U S Department of Justice
Civil Division
3CON
175 N Street, NE
Washington, DC 20002
202-514-4678
robert chandler@usdoj gov
-and-
MARIAMA C SPEARS, ESQ
U S Department of Justice
Drug Enforcement Administration
Office of Chief Counsel
8701 Morrissette Drive
Springfield, Virginia 22152
202-598-6204
mariama c spears@usdoj gov

On behalf of the U S Department of Justice:
JAMES R BENNETT, II, ESQ
UNITED STATES ATTORNEY'S OFFICE
801 West Superior Avenue
Suite 400
Cleveland, Ohio 44113
216-622-3988
james bennett4@usdoj gov

On behalf of Summit County:
MICHAEL E ELSNER, ESQ
MOTLEY RICE, LLC
28 Bridgeside Boulevard
Mt Pleasant, South Carolina 29464
843-216-9250
melsner@motleyrice com
-and-
LINDA SINGER, ESQ
MOTLEY RICE, LLC
401 9th Street, N W
Suite 1001
Washington, D C 20004
202-386-9626
lsinger@motleyrice com

APPEARANCES (CONTINUED):
On behalf of Plaintiffs:
PAUL T FARRELL, JR , ESQ
(Via Teleconference)
GREENE KETCHUM, LLP
419 Eleventh Street
Huntington, West Virginia 25701
304-525-9115
paul@greeneketchum com

On behalf of Purdue Pharma, L P
JENNA C NEWMARK, ESQ
DECHERT, LLP
Three Bryant Park
1095 Avenue of the Americas
New York, New York 10036
212-698-3500
jenna newmark@dechert com
On behalf of Johnson & Johnson and Janssen Pharmaceuticals, Inc
EMILIE K WINCKEL, ESQ
O'MELVENY & MYERS, LLP
1625 Eye Street, N W
Washington, D C 20006
202-383-5129
ewinckel@omm com
-and-
AMY R LUCAS, ESQ
(Via Teleconference)
O'MELVENY & MYERS, LLP
1999 Avenue of the Stars, 8th Floor
Los Angeles, California 90067
310-553-6700
alucas@omm com

APPEARANCES (CONTINUED):

On behalf of Walmart, Inc
NEAL J STEPHENS, ESQ
JONES DAY
1755 Embarcadero Road
Palo Alto, California 94303
650-739-3939
nstephens@jonesday
-and-
PATRICK J BEISELL, ESQ
(Via Teleconference)
JONES DAY
77 West Wacker
Chicago, Illinois 60601
312-269-4066
pbeisell@jonesday com

On behalf of Endo Pharmaceuticals, Inc , Endo Health Solutions, Inc , Par Pharmaceuticals, Inc and Par Pharmaceutical Companies, Inc :
JOSHUA M DAVIS, ESQ
JOANNA PERSIO, ESQ
ARNOLD & PORTER
601 Massachusetts Avenue, N W
Washington, D C 20001
202-942-5000
joshua davis@arnoldporter com
joanna persio@arnoldporter com
On behalf of Rite Aid of Maryland:
JOHN P LAVELLE, JR
MORGAN, LEWIS & BOCKIUS, LLP
1701 Market Street
Philadelphia, Pennsylvania 19103
215-963-4824
john lavelle@morganlewis com
On behalf of Teva Pharmaceutical Industries:
MAUREEN K BARBER, ESQ
(Via Teleconference)
MORGAN LEWIS & BOCKIUS, LLP
One Oxford Centre
Thirty Second Floor
Pittsburgh, Pennsylvania 15219
412-560-7463

APPEARANCES (CONTINUED):
On behalf of Cardinal Health, Inc :
BRAD MASTERS, ESQ
WILLIAMS & CONNOLLY, LLP
725 12th Street, N W
Washington, D C 20005
202-434-5000
bmasters@wc com
On behalf of CVS Indiana, LLC and CVS Rx Services, Inc :
ANTHONY M RUIZ, ESQ
ZUCKERMAN SPAEDER, LLP
1800 M Street, N W
Suite 1000
Washington D C 20036
202-778-1800
aruiz@zuckerman com
On behalf of AmerisourceBergen Drug Corporation:
SHANNON McCLURE, ESQ
REED SMITH, LLP
Three Logan Square, Suite 3100
1717 Arch Street
Philadelphia, Pennsylvania 19103
215-241-7910
smclure@reedsmith com
On behalf of Henry Schein, Inc
BRANDAN MONTMINY, ESQ
(Via Teleconference)
LOCKE LORD, LLP
2200 Ross Avenue
Suite 2800
Dallas, Texas 75201
214-740-8554
brandan montminy@lockelord com

APPEARANCES (CONTINUED):
On behalf of McKesson Corporation:
MEGHAN E MONAGHAN, ESQ
COVINGTON & BURLING, LLP
One CityCenter
850 Tenth Street, N W
Washington, D C 20001
202-662-6000
mmonaghan@cov com
-and-
CHRISTOPHER K EPPICH, ESQ
COVINGTON & BURLING, LLP
1999 Avenue of the Stars
Los Angeles, California 90067
424-332-4764
ceppich@cov com
On behalf of Allergan Finance, LLC:
JENNIFER LEVY, ESQ
CATIE VENTURA, ESQ
KIRKLAND & ELLIS, LLP
655 Fifteenth Street, N W
Washington, D C 20005
202-879-5907
jennifer levy@kirkland com
catie ventura@kirkland com
On behalf of Mallinckrodt and Spec Gx, LLC:
ANDREW O'CONNOR, ESQ
WILLIAM DAVISON, ESQ
ROPES & GRAY, LLP
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199
617-951-7000
andrew o'connor@ropesgray com
william davison@ropesgray com
On behalf of H D Smith:
WILLIAM HAHN, ESQ
(Via Teleconference)
BARNES & THORNBURG, LLP
11 South Meridian Street
Indianapolis, Indiana 46204
317-231-7364
william hahn@btlaw com

APPEARANCES (CONTINUED):
On behalf of Anda, Inc
KRISTINA J MATIC, ESQ
(Via Teleconference)
FOLEY & LARDNER, LLP
777 East Milwaukee, Wisconsin 53202
414-297-5913
kmatic@foley com
On behalf of HBC:
JOSHUA A KOBRIN, ESQ
MARCUS & SHAPIRA, LLP
One Oxford Centre, 35th Floor
301 Grant Street
Pittsburgh, Pennsylvania 15219
412-338-5208
kobrin@marcus-shapira com
On behalf of Walgreen Co and Walgreen Eastern Co , Inc :
SHARON DESH, ESQ
(Via Teleconference)
BARTLIT BECK, LLP
54 West Hubbard Street
Suite 300
Chicago, Illinois 60654
sharon desh@bartlitbeck com
312-494-4445
On behalf of Prescription Supply, Inc :
MARTIN ZACHARY, ESQ
(Via Teleconference)
FOX ROTHSCHILD, LLP
Stone Manor Corporate Center
2700 Kelly Road, Suite 300
Warrington, Pennsylvania 18976
215-918-3680
zmartin@foxrothschild com
On behalf of Discounted Drug Mart:
ERIC WEISS, ESQ
(Via Teleconference)
CAVITCH FAMILO & DURKIN
1300 East 9th Street, 20th Floor
Cleveland, Ohio 44114
216-621-7860

ALSO PRESENT:
Kaitlyn Eekhoff, Research Analyst, Motley Rice
Daniel Russo, Videographer
Solomon Francis, IT Specialist

CONTENTS

EXHIBITS

EXHIBITS (CONTINUED):

(Exhibits included with transcript)

PROCEEDINGS

THE VIDEOGRAPHER: Good morning. We are going on the record at 9:16 a m. on April 11, 2019.

Please note that the microphones are sensitive and may pick up whispering, private conversations and cellular interference. Please turn off all cell phones or place them away from the microphones as they can interfere with the deposition audio. Audio and video recording will continue to take place unless all parties agree to go off the record.

This is Media Unit 1 of the video-recorded deposition of the DEA, appearing on their behalf is Stacy Harper-Avilla, taken by counsel for defendant in the matter of In Re: National Prescription Opiate, filed in the United States District Court, Northern District of Ohio, Eastern Division, Case Number MDL 2804 17-MD-2804.

This deposition is being held at Arnold & Porter located at 601 Massachusetts Avenue, Northwest, Washington, D.C.

My name is Daniel Russo from the

firm Veritext Legal Solutions, I'm your videographer. The court reporter is Bonnie Russo from the firm Veritext Legal Solutions.

Counsel and all present in the room and everyone attending remotely will now state their appearances and affiliations for the record.

MR. O'CONNOR: Andrew O'Connor, Ropes and Gray, for Mallinckrodt LLC and Spec GX.

MR. DAVISON: William Davison of Ropes and Gray for Mallinckrodt LLC and Spec GX.

MR. KOBRIN: Josh Kobrin, Marcus & Shapira for HBC.

MR. EPPICH: Chris Eppich of Covington & Burling for McKesson.

MS. MONAGHAN: Megan Monaghan on behalf of McKesson.

MS. LEVY: Jennifer Levy of Kirkland & Ellis, for the Allergan defendants.

MS. VENTURA: Catie Ventura for the Allergan defendants.

MR. RUIZ: Anthony Ruiz, Zuckerman Spaeder for CVS Indiana, LLC and CVS Rx

Services, Inc.
MS. McCLURE: Shannon McClure, Reed Smith, AmerisourceBergen.
MR. DAVIS: Josh Davis of Arnold & Porter for the Endo and Par defendants.
MS. NEWMARK: Jenna Newmark from Dechert for the Purdue defendants.
MR. LAVELLE: John Lavelle, Morgan Lewis for defendant Rite Aid of Maryland.
MR. MASTERS: Brad Masters, Williams & Connolly, Cardinal Health.
MR. STEPHENS: Neal Stephens, Jones Day, for Walmart.
MS. WINCKEL: Emilie Winckel, O'Melveny and Myers, for the J&J defendants.
MR. ELSNER: Michael Elsner from Motley Rice on behalf of the plaintiffs.
MR. BENNETT: James Bennett from U.S. Attorney's Office, Cleveland, on behalf of the United States and the Department of Justice DEA.
MS. SPEARS: Mariama Spears on behalf of the Drug Enforcement Administration.
MR. CHANDLER: Robert Chandler, United States Department of Justice on behalf

of the United States.
MR. BEISELL: Patrick Beisell, Jones Day on behalf of Walmart.
MS. LUCAS: Amy Lucas, O'Melveny & Myers, on behalf of Janssen Pharmaceuticals and Johnson & Johnson.
MS. MATIC: Kristina Matic on behalf of Anda.
MS. BARBER: Maureen Barber from Morgan Lewis for the Teva defendants.
MS. DESH: Sharon Desh on behalf of Walgreens.
MR. WEISS: Eric Weiss of Cavitch Familo & Durkin on behalf of Discounted Drug Mart.
MR. MARTIN: Zachary Martin, Fox Rothschild, on behalf of Prescriptions Supply.
MR. HAHN: William Hahn on behalf of H.D. Smith from Barnes and Thornburg.
MR. MONTMINY: Brandon Montminy on behalf of the Henry Schein defendants.
THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

STACY HARPER-AVILLA,

being first duly sworn, to tell the truth, the whole truth and nothing but the truth, testified as follows:

THE VIDEOGRAPHER: You may proceed, Counsel.

EXAMINATION BY COUNSEL FOR DEFENDANTS MALLINCKRODT AND SPEC GX LLC
BY MR. O'CONNOR:
Q. Ms. Avilla, good morning.
A. Morning.
Q. I am Andrew O'Connor. I represent Mallinckrodt in this case. I will be asking you some questions on behalf of the manufacturing defendants.
Would you just state your full name for the record.
A. Stacy Harper-Avilla.
Q. And have you ever had your deposition taken before?
A. No.
Q. You can cross that off your bucket list.
So just a few rules of the road

before we get going. First, just to make the court reporter's life a little easier, we're going to try to talk one at a time. I will ask my question and I would just ask that you wait until I finish before you start and I will do the same as you are answering. Rather than shaking your head or nodding, also make sure to give verbal answers.
Does that make sense?
A. Yes.
Q. And if I ask a question and I am not clear or you don't understand, just let me know, and if you don't let me know, I'm just going to assume that you understood the question as I asked it.
Does that make sense?
A. Yes.
Q. Is there anything that would prevent you from testifying completely and truthfully today?
A. No.
Q. And you understand that today you are providing testimony on behalf of the DEA?
A. Yes.
MR. O'CONNOR: I'm going to mark

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Exhibit 1.
(Deposition Exhibit 1 was marked for identification.)
BY MR. O'CONNOR:
Q. This is a notice of deposition.
Have you ever seen this document before?
A. Yes.
Q. And I'm going to ask you to turn to Exhibit B, which is the letter from the U.S. Department of Justice.
Have you ever seen this document before?
A. Yes.
Q. Okay. And do you understand it to be the letter authorizing testimony on certain subjects on behalf of the DEA?
A. Yes.
Q. Let's go ahead and turn to Page 6 and I direct your attention to Topic 13.
It says: "Topic 13. Your practices and procedures related to the establishment of opioid procurement quotas and opioid production quotas for prescription opioids."
Are you authorized by the DEA to

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testify regarding that topic today?
A. Yes.
Q. And I now direct your attention to: "Topic 14, the basis for opioid procurement quotas and opioid production quotas of prescriptions from 1995 to 2018."
Are you authorized by the DEA to provide testimony regarding that topic today?
A. Yes.
Q. Okay.
MR. CHANDLER: I do want to note for the record that Ms. Avilla's authorization extends insofar as the qualifications that are also included in this letter.
MR. O'CONNOR: Understood.
BY MR. O'CONNOR:
Q. If you could turn to Page 9 of that same document.
And look at Topic 3, which reads: "DEA's establishment of quotas for the production of opioids in the United States including aggregate production quotas, individual quotas and procurement quotas, the disclosure of quota to registrants, communications with registrants regarding quota

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requests and the disposition of quota requests and the relationship between quota, suspicious orders, diversion and lawful medical, scientific or industrial channels or use."
Did I read that correctly?
A. Yes.
Q. And are you authorized by DEA to provide testimony on that topic today?
A. Yes.
Q. So when I ask a question, unless I specifically indicate that I am asking for your personal opinion, I am going to be asking for the DEA's answer to that question.
Does that make sense?
A. Yes.
MR. CHANDLER: Andrew, so that I understand, is your initial questioning going to relate to plaintiff's Topic No. 3 as well, or is that only going to be sort of reexamination following the plaintiff's examination?
MR. O'CONNOR: There will probably be some overlap so it could pertain to any one of those three topics.
MR. CHANDLER: Okay. And that is

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understood between you and the plaintiffs? I am trying to understand how this is going to flow back and forth between the two notices.
MR. O'CONNOR: I think we are entitled to question on any one of the topics for which she is authorized, and so we will be proceeding on that basis.
MR. CHANDLER: Okay.
MR. ELSNER: This is Michael Elsner. I'm going to object. You are entitled to ask questions on your topics but not on our topics.
MR. O'CONNOR: I think we would disagree about that, but I think -- let's see how it goes and if we need to resolve it, we can do so offline.
BY MR. O'CONNOR:
Q. Ms. Avilla, what is your current role at DEA?
A. I'm the section chief of United Nations Reporting and Quota Section.
Q. And what do your responsibilities in that role include?
A. The responsibilities are to manage the quotas for controlled substances in

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Schedules I and II, report back to the UN on the U.S. -- usage consumption of those substances as well as for setting the assessments and estimates for items in Schedules III through V, controlled substances in III through V.

Q. How long have you been in that position?

A. Since July of last year.

Q. Before that, did you hold any position at DEA?

A. Yes, I did.

Q. What was that?

A. I was the unit chief of the same section.

Q. You were working with quotas in that role as well?

A. Yes.

Q. What was your position at DEA, if any, before that time?

A. I don't understand the question.

Q. Did you have a job at DEA before that role as unit chief?

A. Yes.

Q. What was that?

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A. Drug science specialist.

Q. Okay. When you were a drug science specialist, did you have any involvement in quota issues?

A. Yes.

Q. Was that role your first at DEA?

A. Yes.

Q. And when did you start in that role?

A. 2008.

Q. So am I correct that you joined the Drug Enforcement Administration in 2008?

A. Correct.

Q. Okay. And since that time, your work has included work on quota-related matters?

A. Yes.

Q. Okay. Did you prepare for this deposition?

A. Yes.

Q. How did you prepare?

A. By reviewing the statute, the regs.

Q. Did you review anything else?

A. Yes. Yes.

Q. What else did you review?

A. Documents for clarification.

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Q. Okay. Do you remember what sorts of documents?

A. No.

Q. Were they e-mails?

A. There were a lot of documents. I don't know. I don't remember precisely what now.

Q. Okay. Without getting into any communications you had with lawyers, what are the names of the people that you spoke with to prepare for this deposition?

A. I spoke with Dr. Chris Sannerud and Mr. Joe Rannazzisi.

Q. Who is Ms. Sannerud?

A. Dr. Sannerud was the section chief before me.

Q. Okay. And is Dr. Sannerud still employed by DEA?

A. No.

Q. When did she leave the DEA?

A. July of last year.

Q. And who is Mr. Rannazzisi?

A. He is a retired DEA special agent.

Q. During your discussions -- or your discussions with Dr. Sannerud, was there anyone

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else in the room or on the phone?

A. I don't understand the question.

Q. When you had discussions to prepare for this deposition with Dr. Sannerud --

A. Yes.

Q. -- was there anyone else in the room with you?

A. The lawyers.

Q. The lawyers. Okay. And when you say, "the lawyers," who do you mean?

A. The DEA lawyers, DEA attorneys.

Q. Okay. Were there any attorneys besides attorneys working for DEA?

A. The ones working for DOJ.

Q. Okay. And besides lawyers working for DOJ, were there any other lawyers?

A. Not that I know of. Not that I remember.

Q. And during your conversations with Mr. Rannazzisi, who was in the room with you or on the phone?

A. In the room where the DOJ and DEA attorneys.

Q. Okay. And besides those attorneys, was there anyone else on the phone or in the

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room?
A. In the room, no.
Q. Were there others on the phone?
A. I don't know.
Q. Do you know if anyone was on the phone?
A. Mr. Rannazzisi was on the phone.
Q. Okay. And regarding the documents that you reviewed in preparation for today, did you choose those documents yourself?
A. Yes.
Q. How did you choose those documents?
A. They were areas that encompassed what was required for the UN reporting and quota section.
Q. Okay. What sort of documents are we talking about?
MR. CHANDLER: I'm going to step in here.
To the extent that your answer requires you to disclose any of our communications or communications with any of the government lawyers, I will instruct you not to answer.
If you can answer subject to that,

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that caveat, you can answer.
BY MR. O'CONNOR:
Q. So without getting into the communications with your lawyers, what sorts of documents did you select?
A. I can't answer.
Q. I'm sorry?
A. I can't answer.
Q. And why can't you answer?
A. A lot of that is communication shared with the attorneys.
Q. Okay. In preparing for today's deposition, did you speak with anyone else at DEA other than the lawyers, Dr. Sannerud and Mr. Rannazzisi?
A. No.
Q. Did you speak with anyone else who has testified previously in this matter?
A. Not to my knowledge.
Q. Did you speak with anyone outside DEA in preparing for this deposition, other than those we've already discussed?
A. No.
Q. Okay. About how much time did you spend preparing for today?

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A. I don't know. I didn't quantify it.
Q. Okay. Roughly how many meetings did you have with DOJ or DEA attorneys about today?
A. I don't have an exact number.
Q. How about an estimate?
A. Less than ten.
Q. Less than ten. Okay. About how long were those meetings?
A. They were usually several hours.
Q. Okay. When you say, "less than ten," do you think there was more than five?
A. Probably.
Q. Okay. All right. So I want to turn back to your responsibilities as unit chief of the UN reporting and quota section.
In that role, what responsibility did you have with respect to establishing quotas for Schedule I and II controlled substances?
A. To review the incoming applications, to review documentation, review and assess whether it was scientifically accurate.
Q. Okay. Who did you report to when you were unit chief?
A. Dr. Chris Sannerud.

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Q. Okay. And did there come a time where you were promoted to section chief?
A. Yes.
Q. And at that time, who did you report to?
A. Susan Gibson.
Q. And what is Ms. Gibson's position?
A. I'm not sure.
Q. Okay.
A. I'm not sure. She is in New Jersey at this point.
Q. Okay. Is she your current supervisor?
A. No.
Q. Who is your current supervisor?
A. Raymond Brown, Special Agent Raymond Brown.
Q. And what is his position at DEA?
A. Deputy assistant administrator.
Q. In your role as unit chief and now section chief, did you come to have an understanding of the DEA's practices and procedures related to the establishment of quotas?
A. Yes.

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Q. And did that include -- did your understanding include the procedures and practices specifically related to aggregate production quota?
A. Yes.
Q. And does it also include practices and procedures related to the procurement quota process?
A. Yes.
Q. Does it also include individual manufacturing quotas?
A. Yes.
Q. In those positions, did you also gain an understanding of the basis or the reasons why those quotas were set where they were?
A. Yes.
Q. And through your work, did you also get an understanding of the reasons the DEA had for increasing the quota from year to year with respect to certain substances?
MR. CHANDLER: Objection. Vague.
BY MR. O'CONNOR:
Q. You can answer the question.
A. Each year the quota is built

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individually. It's not a year-to-year situation.
Q. Okay. And in any given year during your time at DEA, you understood the reasons the quota was set at the level that it was set at; is that fair?
A. Yes.
MR. CHANDLER: Objection. Vague.
BY MR. O'CONNOR:
Q. Are you familiar with the term "closed system of distribution?"
A. Yes.
Q. What do you understand that term to mean?
MR. CHANDLER: Objection. Scope.
You can answer.
THE WITNESS: It means that the controlled substance is monitored within a system set up by the Controlled Substances Act from the manufacturer down to the pharmacy level in the ultimate locations.
BY MR. O'CONNOR:
Q. And the players at those various levels that you just mentioned are all DEA registrants, correct?

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MR. CHANDLER: Objection. Vague.
THE WITNESS: From the manufacturers to the pharmacy, yes, they should be.
BY MR. O'CONNOR:
Q. Okay. So manufacturers, distributors, pharmacies are all DEA registrants, correct?
A. If they handle controlled substances, yes.
Q. I want to turn to manufacturers for a minute.
In order to manufacture controlled substances with approval from DEA, what steps does a manufacturer need to take?
MR. CHANDLER: Objection. Vague. Scope.
BY MR. O'CONNOR:
Q. You can answer.
A. I don't understand the question.
Q. Okay. Do manufacturers need to request a quota grant before they can produce controlled substances?
A. Yes.
Q. Are manufacturers permitted to manufacture any more of a controlled substance

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than DEA permits through its quota process?
A. No.
Q. Is it fair to say that DEA has the ability to decline to provide any given manufacturer with a quota grant?
A. I don't understand the question.
Q. Is DEA required to grant manufacturers quota?
MR. CHANDLER: Objection. Vague.
THE WITNESS: I don't understand the question.
BY MR. O'CONNOR:
Q. So in your role, are you involved with the consideration and approval of quota requests?
A. Yes.
Q. Are you required to approve every request?
A. No.
Q. That's because the DEA does not -- is not required to approve every request, correct?
A. Correct.
Q. Are you familiar with any statute that sets forth DEA's authority to grant quota?

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A. I don't understand the question.
Q. Is there any statute that grants the Drug Enforcement Administration the authority to set quota for controlled substances?
A. Yes.
Q. Are you familiar with that statute?
A. Yes.
Q. Are there any regulations that DEA has promulgated that set forth the process for setting the quota for controlled substances?
A. Yes.
Q. And in your role as unit chief and then section chief, was one of your responsibilities to apply the processes that were described by statute and regulation in determining the amount of quota?
MR. CHANDLER: Objection. Vague. Compound.
BY MR. O'CONNOR:
Q. You can answer.
A. Yes.
Q. Are you familiar with the term "aggregate production quota?"
A. Yes.
Q. What does that term mean?

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A. In summary, it is the maximum amount that the United States actually needs for its domestic needs, for legitimate, medical, scientific, research needs, exportation needs and inventory allowances.
Q. Okay. Does DEA determine what that number is on an annual basis?
MR. CHANDLER: Objection. Vague. You can answer.
THE WITNESS: I don't understand the question.
BY MR. O'CONNOR:
Q. Is DEA responsible for determining the aggregate production quota?
A. DEA is the agency that publishes it, but we work in concert with other agencies.
Q. Okay. What other agencies do you work with?
A. FDA.
Q. Any other agencies?
A. When necessary, yes.
Q. What would those other agencies be?
A. Those within the bounds of DOJ and HHS.
Q. When you work with FDA in connection

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with quota, what is the nature of the FDA's involvement?
MR. ELSNER: Objection.
MR. CHANDLER: I will object. Vague as to time.
BY MR. O'CONNOR:
Q. Do you recall any times in which FDA was involved in discussions regarding quota?
A. I don't understand the question.
Q. You mentioned that at times, you consulted with FDA in connection with quota, correct?
A. Yes.
Q. When did that happen?
MR. CHANDLER: Objection. Vague. You can answer.
THE WITNESS: By statute, by FDA statute, they are required to consult with us. We are required to have a dialogue however it takes place.
BY MR. O'CONNOR:
Q. And did DEA comply with its obligation to have discussions with FDA?
A. Yes.
Q. Did DEA consult with FDA in

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connection with the aggregate production quota every year?
A. I can't guarantee every year, but yes, as far as I know, I have seen documentation for almost every year.
Q. Okay. What form did that documentation take?
A. A letter.
Q. Okay. Would there be discussions between the FDA and DEA prior to FDA sending that letter?
A. Not that I'm aware of. There may be, but I don't know of any that were documented.
Q. Okay. Besides yourself, how many others at DEA work on quota-related issues?
MR. ELSNER: Objection. Timing.
BY MR. O'CONNOR:
Q. Today -- strike that.
Today, how many people at DEA work on quota-related issues?
MR. CHANDLER: Objection. Vague.
THE WITNESS: I'm not sure I understand the question.
BY MR. O'CONNOR:

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Q. You are not the only person at DEA that works on quota, correct?
A. Correct.
Q. Okay. Roughly how many other people are involved in the process of setting aggregate production quotas?
A. There are several people involved in several different sections for setting an aggregate production quota and I don't know who all of the people are, just the sections that they go through.
Q. Okay. When you were unit chief, how many people approximately worked in your section -- in your unit. Sorry.
A. It varied over the years.
Q. So when you first started as unit chief, approximately how many people worked in your unit?
A. Four or five people.
Q. Okay. Were they full-time employees?
A. Yes.
Q. Did that number change over time?
A. Yes.
Q. When did it change?

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A. I don't recall. It just -- it changed when people made clearance.
Q. Did the group get bigger or smaller?
A. Bigger.
Q. Okay. Roughly how big did it get?
A. I don't understand the question.
Q. When the group was at its biggest, how many people were in it?
A. Ten, 12 people.
Q. Were all of those individuals involved in the process of determining quota?
A. Yes.
Q. Okay. Did those individuals who were involved in the quota process receive any training regarding quota?
MR. CHANDLER: Objection. Vague.
THE WITNESS: I'm not sure I understand the question.
BY MR. O'CONNOR:
Q. Did the people who worked on quota have the training they needed in your view to do their job?
MR. CHANDLER: Objection. Vague. Scope.
THE WITNESS: Yes.

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BY MR. O'CONNOR:
Q. Safe to say that as the unit chief, if you felt they were not able to discharge their duties, you would have done something about that, right?
MR. ELSNER: Objection.
THE WITNESS: I would have provided extra training, yes.
BY MR. O'CONNOR:
Q. You mentioned that at times, DEA communicated with HHS in connection with the quota.
On what subjects would DEA communicate with HHS when it came to quota issues?
A. So I mentioned that DEA communicated with FDA within HHS on quota issues.
Q. Were there any other agencies or departments within HHS that DEA communicated with on quota issues?
MR. ELSNER: Objection.
BY MR. O'CONNOR:
Q. You can answer the question.
A. There would have been SAMSHA at the time probably.

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Q. What is SAMSHA?
A. I don't remember the full name.
Q. Fair enough. Do you know generally speaking what SAMSHA does?
A. Substance abuse and mental health.
Q. Okay. Between 1995 and 2018, was DEA -- or did DEA consult with SAMSHA on a regular basis in connection with quota?
MR. CHANDLER: Objection. Vague.
THE WITNESS: I don't understand the question.
BY MR. O'CONNOR:
Q. Did DEA communicate with SAMSHA more than once?
A. Yes.
Q. Did DEA communicate with SAMSHA on a yearly basis regarding quota?
A. Probably, not directly.
Q. If not directly, how would DEA communicate with SAMSHA?
A. SAMSHA's concerns were usually placed in FDA's letter to DEA.
Q. Okay. Would DEA consider the FDA's input when determining the aggregate production quota?

A. Yes.
Q. And would DEA consider SAMSHA's input when determining the aggregate production quota?
A. Yes, when it was there.
Q. Okay. What else would DEA consider when determining the aggregate production quota?
A. DEA would also consider the manufacturer's quota application, changes in marketplace, manufacturer's changes to their processes, export requirements, inventory allowances that needed to be done, new indication, removal of indications, changes in FDA approval. Or changes in -- yeah, changes in FDA approval.
Q. Okay. Between 1995 and 2018, did the DEA consider all those factors when setting quota?
A. Yes, that's part of the whole statement.
Q. So if someone claimed that DEA made a decision about quota based on only one of those factors, would you agree with them?
MR. CHANDLER: Objection. Vague.

Scope.
MR. ELSNER: Objection.
THE WITNESS: I would not agree with them.
BY MR. O'CONNOR:
Q. DEA sets aggregate production quotas for each individual class of controlled substances; is that fair?
A. DEA sets quota for each class of Schedule I or Schedule II controlled substance
Q. Fair enough. And what do you mean when you say, "class of controlled substance?"
A. A class is the basic substance.
Q. Would that include things like oxycodone?
A. Yes.
Q. Hydrocodone?
A. Yes.
Q. Hydromorphone?
A. Yes.
Q. Morphine?
A. Yes.
Q. Oxymorphone?
A. Yes.
Q. And when DEA is setting the

aggregate production quota for each of those individual classes, does it consider all those factors that you mentioned a moment ago?
A. Yes.
Q. Let's talk for a minute about manufacturing quotas.
What do you understand the term "manufacturing quota" to mean?
A. It is the quota granted to a bulk manufacturer who synthesizes or extracts aggregate -- active pharmaceutical ingredients from either a noncontrolled substance or a plant or from one controlled substance into another.
Q. Okay. How does DEA determine what manufacturing quotas to grant?
MR. CHANDLER: Objection. Vague.
MR. ELSNER: Objection.
BY MR. O'CONNOR:
Q. You can answer.
A. For the manufacturing quota, it is built on their customers and their manufacturing processes, as well as inventory allowances and any other FDA notifications that we have received.

Q. Okay. And couldn't the -- can any given manufacturer make more of a particular class of controlled substances than the DEA permits?
MR. ELSNER: Objection.
THE WITNESS: I think there is a difference between "can" and "should."
BY MR. O'CONNOR:
Q. Fair enough. Would it be legal for a manufacturer to produce more of a controlled substance than permitted by its DEA quota?
A. Not to my knowledge, it's not legal.
Q. Okay. And are you aware of any circumstances in which a manufacturer did make more than what it was permitted?
A. It has occurred on occasion and DEA has taken action with the manufacturer.
Q. Okay. Is it fair to say that DEA takes steps to ensure that manufacturers don't make more than what they are permitted to under their DEA quota?
MR. CHANDLER: Objection. Scope.
THE WITNESS: Can you repeat the question.
BY MR. O'CONNOR:

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Q. Sure. Is it fair to say that DEA takes steps to ensure that manufacturers don't make more than what they are permitted to under their DEA quota?
MR. CHANDLER: Same objection.
THE WITNESS: When DEA has notice of it, yes.
BY MR. O'CONNOR:
Q. Are you familiar with the term "procurement quota?"
A. Yes.
Q. What is procurement quota?
A. Procurement quota is the maximum amount of quota -- maximum amount of material a manufacturer can obtain.
Q. Is the amount of -- strike that.
DEA sets the procurement quota for each manufacturer, correct?
A. Of a Schedule I or II controlled substance, yes.
Q. How does DEA determine how to set the production quota for any given manufacturer? I'm sorry, strike that.
How does DEA determine the procurement quota for any given registrant?

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A. It would be based on their business activity which is individual to the manufacturer.
Q. Okay. When you say, "business activity," what do you mean?
A. It is based on the rationale that they provide DEA on the reason why they need quota.
Q. What is the -- is it fair to say that one of the purposes of granting procurement quota is to ensure an adequate and uninterrupted supply of medications?
A. It is one purpose.
Q. Is it also fair to say that if DEA did not grant procurement quotas, there would be a risk to the adequate and uninterrupted supply of medications?
MR. CHANDLER: Objection. Vague.
THE WITNESS: I don't understand the question.
BY MR. O'CONNOR:
Q. Okay. Unlike the adequate production quota, procurement quotas are granted on an individual class of controlled substances, correct?

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A. Correct.
Q. So, for example, oxycodone would have -- strike that.
So, for example, there would be a specific procurement quota grant to a manufacturer for oxycodone?
A. Correct.
Q. That would be separate from any procurement grant for Hydrocodone?
A. Correct.
Q. And DEA would make an assessment about the appropriate procurement quota for each molecule separately?
A. Yes.
Q. And a manufacturer would not be allowed to procure more of that molecule than the DEA permitted, correct?
A. Can I have the question repeated.
Q. Sure. And a manufacturer would not be allowed to procure more of that molecule than the DEA permitted, correct?
A. I think there is a difference between would or ability to and should they, when the processes work, no they cannot do that. If the process does not work, then they

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may.
Q. Okay.
MR. O'CONNOR: I'm going to mark Exhibit 2.
(Deposition Exhibit 2 was marked for identification.)
BY MR. O'CONNOR:
Q. Do you recognize this document?
A. Yes.
Q. What is it?
A. It is a page from the C.F.R.
Q. Okay. Was this a portion of the C.F.R. that you used in connection with your role as unit chief and section chief?
MR. CHANDLER: Objection. Vague as to time.
THE WITNESS: I don't understand the question.
BY MR. O'CONNOR:
Q. Okay. When you were working on quota issues, did you ever refer to this regulation?
MR. CHANDLER: Same objection.
THE WITNESS: Can I have the question back.

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BY MR. O'CONNOR:
Q. Sure. When you were working on quota issues, did you ever refer to this regulation?
A. When I was working on the aggregate production quota, then this section that you printed, yes.
Q. And specifically, I would like to talk about Section 1303.11(b), which says: "In making this determination, the administrator shall consider the following factors."
Do you see that?
A. Yes.
Q. Okay. And then it goes on to list five items.
The first is: "Total net disposal of the class by all manufacturers during the current and two preceding years."
Did DEA consider that factor when setting the aggregate production quotas between 1995 and 2018?
A. Yes.
Q. And what does it mean to say the "total net disposal of the class?"
A. So total net disposal would be the

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aggregate disposal disposition of all the manufacturers, not counting their manufacturing losses or their returns to other manufacturers.
Q. Okay. Okay. No. 2 says: "Trends in the national rate of net disposal of the class."
What does that mean?
A. Trends in national rate would be changes in disposal rates.
Q. How would DEA take into account trends in the national rate of net disposal when determining aggregate production quotas?
A. The main factor would be from FDA.
Q. Okay. And in each year from 1995 to 2018, did DEA, in fact, consider the trends in the national rate of net disposal of the class when setting aggregate production quotas?
A. Yes.
Q. No. 3 says: "The total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation."
What does that mean?
A. Total inventory would be the amount that the manufacturers have remaining after

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they have manufactured a substance but had not disposed of it.
Q. Okay. And did the DEA take that into account each year between 1995 and 2018 when setting the aggregate production quota?
A. Yes.
Q. No. 4 says: "Projected demand for such class as indicated by procurement quotas requested pursuant to Section 1303.12."
What does that mean?
A. Projected demand would be the amount of material being requested through procurement quotas.
Q. And did the DEA consider that factor each year in setting aggregate production quota?
A. Yes.
Q. No. 5 says: "Other factors affecting medical, scientific research and industrial needs in the United States and lawful export requirements as the administrator finds relevant."
What other factors did DEA consider when setting the aggregate production quota?
MR. CHANDLER: Objection. Form.

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THE WITNESS: It would depend on the substance.
BY MR. O'CONNOR:
Q. So by way of example of oxycodone, what other factors contemplated by Subsection 5 did the DEA consider when setting aggregate production quota?
MR. CHANDLER: Objection. Vague.
THE WITNESS: It would be the number of manufacturers, their actual use and need for the material, known diversion, known abuse.
BY MR. O'CONNOR:
Q. And were those factors you just listed considered every year between 1995 and 2018?
MR. ELSNER: Objection.
THE WITNESS: When there was data, yes.
BY MR. O'CONNOR:
Q. Were there any years in which there was not data on those factors you named?
MR. CHANDLER: Objection. Vague. Scope.
THE WITNESS: I didn't memorize every year so I don't know.

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BY MR. O'CONNOR:
Q. But speaking here today with respect to the DEA practices on setting quota, were there any years in which DEA did not consider the number of manufacturers when setting aggregate production quota?
MR. CHANDLER: Objection. Vague. Scope.
THE WITNESS: It's a factor to be considered.
BY MR. O'CONNOR:
Q. Were there any years between 1995 and 2018 when DEA did not consider the actual use and need for the material?
A. It is still --
MR. CHANDLER: Objection. Vague. Scope.
You can answer.
THE WITNESS: It is still a factor.
BY MR. O'CONNOR:
Q. Were there any years in which DEA did not consider known diversion when determining the aggregate production quota?
MR. CHANDLER: Objection. Vague. Scope.

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THE WITNESS: It's still a factor.
BY MR. O'CONNOR:
Q. And were there any years between 1995 and 2018 in which DEA did not consider known abuse when setting aggregate production quota?
MR. CHANDLER: Objection. Vague. Scope.
THE WITNESS: True abuse lay with the FDA so it's a factor once again.
BY MR. O'CONNOR:
Q. Between 1998 and 2018, did the DEA consider changes in the currently accepted medical use and treatment with the class when considering or setting the aggregate production quota?
A. As set forth by FDA, yes.
Q. Between 1995 and 2018, did DEA consider the economic and physical availability of raw materials for use in manufacturing --
MR. CHANDLER: Objection. Vague.
BY MR. O'CONNOR:
Q. -- when setting the aggregate production quota?
A. When provided with that information,

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yes.
Q. And in each year from 1995 to 2018, did DEA consider the potential disruptions to production when setting the aggregate production quota?
MR. CHANDLER: Objection. Vague.
THE WITNESS: It's -- it can be considered when it's known. Potential is not known.
BY MR. O'CONNOR:
Q. If there was, for example, a recall in the marketplace of a particular kind of drug, would DEA consider that when setting the aggregate production quota?
A. If the recall was verified through FDA, then yes.
Q. Who at DEA was responsible for communicating with FDA regarding aggregate production quota?
A. The DEA sends a letter signed by Mr. Rannazzisi to FDA requesting that information.
Q. On the occasions that Mr. Rannazzisi requested the information, did FDA respond?
A. Yes, in a letter form back.
Q. Would DEA consider those letters

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from FDA when making a decision on aggregate production quota?
A. Yes.
MR. O'CONNOR: We have been going a little over an hour. Should we take a break?
THE VIDEOGRAPHER: We are going off the record. This is the end of Media Unit No. 1. The time is 10:23.
(A short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. This is the beginning of Media Unit No. 2. The time is 10:57.
You may proceed, Counsel.
MR. O'CONNOR: Thank you. I'm going to mark Exhibit 3.
(Deposition Exhibit 3 was marked for identification.)
BY MR. O'CONNOR:
Q. Ms. Harper-Avilla, are you familiar with this document?
A. I'm aware of this document.
Q. Have you seen it before?
A. I have.
Q. Would you mind turning to Page 10. On Page 10, the report reads in

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part: "In establishing APQs for each basic class of Schedule I and Schedule II controlled substances, DEA considers information from many sources, including," and then it lists several sources of information.

First of all, would you agree with the statement that in setting aggregate production quotas, DEA considers information from many sources?

A. Yes.

Q. I just want to walk through each of these bullets.

In setting the aggregate production quota, does DEA consider manufacturer's production history and anticipated needs?

A. As provided to DEA, yes.

Q. And does DEA consider in determining aggregate production quota estimates from IMS Health on retail consumption based on prescriptions dispensed?

A. Yes.

Q. In each year from 1995 through 2018, did DEA consider information from IMS Health on retail consumption based on prescriptions dispensed when setting aggregate production

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quotas?

A. For the years that IMS Health was in existence, yes. I don't know what was used prior to that.

Q. Okay. During which years was IMS Health used?

MR. ELSNER: Objection.

THE WITNESS: For the years in which they had a contract with DEA.

BY MR. O'CONNOR:

Q. What years were those?

A. I am not in charge of contracts. I don't know the answer.

Q. Okay. But in connection with the DEA's practice of setting aggregate production quota, during what years did DEA use estimates from IMS Health on retail consumption based on prescriptions dispensed?

MR. ELSNER: Objection.

THE WITNESS: For the years in which DEA had a contract with IMS Health, I am not familiar with these -- those years.

BY MR. O'CONNOR:

Q. Can you provide an estimate?

A. No.

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Q. Did you use it last year?

A. IMS Health no longer exists.

Q. Okay. Did the DEA obtain any data to use in its place?

MR. ELSNER: Objection.

MR. CHANDLER: Objection. Vague.

THE WITNESS: DEA has a contract with another vendor, yes.

BY MR. O'CONNOR:

Q. Which vendor is that?

A. IQVIA.

Q. And does IQVIA provides estimates on retail consumption based on prescriptions dispensed?

A. Yes.

Q. When you became unit chief in 2008, did DEA use IMS data on retail consumption based on prescriptions dispensed when setting the aggregate production quota?

A. Yes.

Q. And in every year between 2008 and the time when DEA switched to IQVIA data, did DEA use IMS Health data when setting the aggregate production quota?

MR. ELSNER: Objection.

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THE WITNESS: Yes.

BY MR. O'CONNOR:

Q. So just to be clear, in the years 2009, '10, '11, '12, '13, '14, '15, '16 and '17, DEA used IMS Health data on retail consumption based on prescriptions dispensed when determining the aggregate production quota?

MR. CHANDLER: Objection. Misstates prior testimony.

THE WITNESS: Because I'm not aware of when the contract changed, I'm not sure which year IMS Health ceased to exist and became IQVIA.

BY MR. O'CONNOR:

Q. But in every year between 2008 and 2018, DEA used data either from IMS or IQVIA when setting the annual production quota, correct?

A. It was a factor and consideration, yes.

Q. And prior to 2008, did DEA consider IMS Health data when setting the aggregate production quota?

A. If the contract existed, yes, it

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did.
Q. And were there any years in which you believe the contract did not exist between 1995 and 2008?
A. I don't know when IMS Health came into existence so I cannot speak to that.
Q. During the years in which DEA used IMS Health data or IQVIA data, did it use that data when setting the aggregate production quota for oxycodone?
MR. CHANDLER: Objection. Scope.
THE WITNESS: The estimate was a factor, a single factor in a multi-factor system.
BY MR. O'CONNOR:
Q. And during the years in which DEA used IMS Health data or IQVIA data, did it use that data when setting the aggregate production quota for Hydrocodone?
MR. CHANDLER: Objection. Scope.
THE WITNESS: It was a factor in it.
BY MR. O'CONNOR:
Q. And during the years in which DEA used IMS Health data or IQVIA data, did it use that data when setting the aggregate production

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quota for every other basic class of controlled substances for which quota was granted?
MR. CHANDLER: Objection. Scope.
THE WITNESS: Can I have the question again.
BY MR. O'CONNOR:
Q. Sure. During the years in which DEA used IMS Health data or IQVIA data, did it use that data when setting the aggregate production quota for every other basic class of controlled substances for which quota was granted?
A. No.
Q. For which classes of controlled substances did DEA not use IMS Health or IQVIA data when setting the aggregate production quota?
MR. CHANDLER: Objection. Scope.
THE WITNESS: For those that are not FDA approved.
BY MR. O'CONNOR:
Q. But for all those classes of controlled substances that are FDA approved, DEA considered IMS Health or IQVIA data when setting the aggregate production quota, correct?

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MR. CHANDLER: Objection. Scope.
THE WITNESS: Only for domestic prescription data, yes.
BY MR. O'CONNOR:
Q. And they considered that in every year from at least 2008 to the present, correct?
MR. CHANDLER: Objection. Scope.
THE WITNESS: Prescription data would be considered as a one point, one single factor in a multi-factored system, yes.
BY MR. O'CONNOR:
Q. And it would be considered in each and every year between 2008 and 2018, correct?
MR. CHANDLER: Objection. Scope.
THE WITNESS: If the data existed.
BY MR. O'CONNOR:
Q. Were there any years between 2008 and 2018 in which the data did not exist?
MR. ELSNER: Objection.
THE WITNESS: When FDA changed treatment marketing, then the data did not exist.
BY MR. O'CONNOR:
Q. What do you mean by that?

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A. If FDA decided that something needed to be pulled from the market, then it did not exist. If FDA decided that they were granting a new product to the market, the data did not exist.
Q. Okay. But for those classes of controlled substances that were already on the market, the DEA considered IMS Health data or IQVIA data in each and every year between 2008 and 2018 when determining aggregate production quota, correct?
MR. CHANDLER: Objection. Scope.
THE WITNESS: If the FDA pulled a product in the middle of the year, then no, we could not consider already granted prescription data foreset [sic] in the next year.
BY MR. O'CONNOR:
Q. Were there any products that you can recall that were pulled mid-year?
A. Yes.
Q. What were those?
A. Can I have a moment, please, with my attorney?
Q. You can answer the question unless you have a question about privilege.

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MR. CHANDLER: Is there a question of communication or privilege?
Go off the record for a minute.
MR. O'CONNOR: Sure.
THE VIDEOGRAPHER: We are going off the record. The time is 11:00.
(A short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 11:06.
You may proceed, Counsel.
BY MR. O'CONNOR:
Q. So Ms. Harper-Avilla, when we left, I think you were -- needed to consult with your attorney.
Do you have an answer to the question?
A. Can I have the question back, please.
Q. We will strike that question.
Take a look at the next bullet point on the list.
It says: "Data from DEA's internal system for tracking controlled substances transactions known as the Automation of Reports and Consolidated Order System, ARCOS."

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Did DEA consider data from ARCOS in each year between 1995 and 2018 when determining the aggregate production quota?
A. Yes.
Q. And did it use data from ARCOS in determining the aggregate production quota in each of those years for every opioid product for which it granted quota?
A. Where it was known that the data was valid, yes.
Q. Were there any products for which the data was not valid in any of those years between 1995 and 2018?
MR. ELSNER: Objection.
THE WITNESS: The data is only as good as the manufacturers put into it and there were errors with that in some cases.
BY MR. O'CONNOR:
Q. Where does the data from ARCOS come from?
MR. CHANDLER: Objection.
I'm going to instruct the witness not to answer. She is not designated to testify about ARCOS.
BY MR. O'CONNOR:

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Q. Were there any years in which you understood the ARCOS data to be invalid?
MR. ELSNER: Objection.
MR. CHANDLER: Objection.
And I will instruct the witness not to answer.
You can ask about the quota section's use of ARCOS data, but as far as the validity or operation of ARCOS, no, we will oppose that.
BY MR. O'CONNOR:
Q. When considering the aggregate production quota, were there any years in which DEA did not rely on ARCOS data for a particular substance?
A. The data was considered, but it is a factor.
Q. And the data was considered in each and every year between 1995 and 2018, correct?
A. Within its known limitations of the data, yes.
Q. And it was considered for each and every opioid product for which quota was granted during those years, correct?
A. Within the limitations, yes.

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Q. And what are those limitations?
A. That the data may not always be valid because of a manufacturing input.
Q. Were there any years when you did not feel comfortable considering that data because you believed it was unreliable?
A. The data was always considered suspect for each year.
Q. What do you mean when you say, "it was considered suspect?"
A. That the data was only as good as the input from the manufacturers.
Q. The next bullet says: "Past history of the quota granted for each substance from YERS/QMS."
What is YERS/QMS?
A. It's a year-end reporting system, quota management system.
Q. That's maintained by DEA?
A. Yes.
Q. And what data does it include?
A. Manufacturing and disposition data for manufacturers who are registered for Schedule I and II controlled substances as well as internationally controlled III through V.

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Q. Okay. The next bullet says: "Estimates of the projected medical, scientific and reserve stock needs provided by FDA's controlled substances staff."

Were such estimates considered when determining the aggregate production quota?

A. For every year that a letter existed, yes.

Q. And between the years 1995 and 2018, are you aware of any years in which FDA did not provide a letter?

A. I am not aware.

Q. And did DEA consider the estimates provided by FDA when determining the aggregate production quota of each and every opioid product for which it granted quota?

A. Yes.

Q. How would DEA receive estimates of the projected medical, scientific and reserve stock needs from the FDA?

A. In a letter.

Q. The same letter, same type of letter you mentioned earlier today?

A. It's the exact letter.

MR. O'CONNOR: Counsel, I don't know

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that we received those letters but we make a request on the record to get them.

MR. CHANDLER: Okay. We can discuss that afterwards.

BY MR. O'CONNOR:

Q. And did the DEA consider any other estimates of the projected medical, scientific and reserve stock needs besides the ones provided by FDA when determining aggregate production quota?

A. Yes. Those provided by the companies themselves.

Q. In addition to estimates provided to the DEA of the projected medical, scientific and reserve stock needs, did DEA come to its own determination of the projected medical, scientific and reserve stock needs when considering aggregate production quota?

A. DEA took into account the manufacturing needs in order to make those projected accounts from FDA.

Q. I'm sorry. I'm not sure I understand the answer.

Could you just explain?

MR. ELSNER: Objection.

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THE WITNESS: FDA's projected medical, scientific needs did not include manufacturing needs in terms of yield and losses from the manufacturers. DEA had to consider that in order to reach that estimate.

BY MR. O'CONNOR:

Q. So in addition to the estimates provided by FDA, the DEA also considered the amounts needed to account for yield or loss in production?

A. Yes.

Q. Is that fair?

Okay. And is it fair to say that under the regulations regarding quota, DEA was responsible for setting quota at a level that was consistent with the medical, scientific and industrial needs of the United States?

A. Yes. And the reserve stock.

Q. The last bullet says: "Data on the diversion of controlled substances, such as information from case seizures and national databases of drug evidence."

Did the DEA consider that data when establishing aggregate production quota in each and every year between 1995 and 19 -- or in

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2018?

MR. ELSNER: Objection.

THE WITNESS: When the data was available, yes.

BY MR. O'CONNOR:

Q. During which years between 1995 and 2018, did DEA not consider data on the diversion of controlled substances when setting the aggregate production quota?

MR. ELSNER: Objection.

THE WITNESS: When the data was not available.

BY MR. O'CONNOR:

Q. In what years was the data not available?

MR. ELSNER: Objection.

THE WITNESS: When the case was still open against a manufacturer.

BY MR. O'CONNOR:

Q. So let's talk for a moment about what data on diversion of controlled substances was considered.

When setting the aggregate production quotas, what data on diversion did the agency use?

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A. Internal data.
Q. What sorts of internal data?
A. Known quantifiable seizure data, known quantifiable information received from state and local law enforcement agencies or labs.
Q. And to the extent DEA had data on diversion that was quantifiable, did it consider that data in connection with setting the aggregate production quotas for opioids?
A. Yes.
Q. Did it consider that data in setting the aggregate production quota for opioids in each and every year between 1995 and 2018?
A. Where it existed, yes.
Q. Were there any years during that time period where, to your knowledge, the data did not exist?
MR. CHANDLER: Objection. Vague. You can answer.
THE WITNESS: There are years where the data was not broken out by controlled substance, so we could not quantify it per controlled substance, and that led to other issues.

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BY MR. O'CONNOR:
Q. Where the data could not be broken out by controlled substance, did the DEA still consider that information when setting aggregate production quota?
A. It could not be attributed to a specific controlled substance, so no.
Q. In what years did the data not allow the diversion data to be attributed to a particular substance?
MR. ELSNER: Objection.
THE WITNESS: It varied in the years based on how the data was submitted to DEA. Once again, it's not our internal data.
BY MR. O'CONNOR:
Q. And who were you receiving the data from?
A. It would have been state and local labs.
Q. Are you aware of any year between '95 -- 1995 and 2018 in which diversion data regarding oxycodone was not considered when setting the oxycodone aggregate production quota?
A. I am not aware when it was not considered.

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Q. Are you aware of any year between 1995 and 2018 in which diversion data regarding Hydrocodone was not considered when setting the Hydrocodone aggregate production quota?
MR. ELSNER: Objection.
THE WITNESS: I'm not aware of when it was not considered.
BY MR. O'CONNOR:
Q. Are you aware of any year between 1995 and 2018 in which diversion data regarding any other opioid product was not considered when setting aggregate production quotas?
A. I am not aware, if it's spelled out a controlled substance, then we considered it.
Q. So to be clear, was there any year between 1995 and 2018 in which DEA did not consider diversion data involving any other opioid product when setting aggregate production quotas?
MR. ELSNER: Objection.
THE WITNESS: DEA considered diversion data when it was a specific controlled substance, not a vague term opioid.
BY MR. O'CONNOR:

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Q. Okay. But when DEA had data on those specific opioids, it considered that diversion data when setting the aggregate production quota, correct?
A. Yes, if we have the data.
Q. And during what years did DEA not have the data?
A. I don't recall.
Q. Do you recall any year in which DEA did not have that data?
MR. ELSNER: Objection.
THE WITNESS: There were -- there was a time frame where the data was not specific to the controlled substance. It was just termed opioid or termed narcotic, and in which case, we could not consider it for the individual scope.
BY MR. O'CONNOR:
Q. During what years or what time frame did you receive the data that was just termed opioid or narcotic and not broken out by individual molecule?
A. There are various times. I don't recall specific ones.
Q. So you recall no specific times in

which the data wasn't broken out?
MR. ELSNER: Objection.
MR. CHANDLER: Objection. Scope.
BY MR. O'CONNOR:
Q. You can answer the question.
A. The data was whatever it was at the time. If it was broken out by controlled substance, we had it. If it was just termed narcotic, we could not use it for the specific controlled substance, and that could occur at any point in time because we did not input the data, that came from state and local labs.
Q. Okay. If we had to find out which years DEA wasn't able to use the individualized data, how would we do that?
MR. CHANDLER: Objection. Scope.
THE WITNESS: I'm not sure. I don't know.
BY MR. O'CONNOR:
Q. Is there anyone else at DEA who might know the answer to that question?
MR. ELSNER: Objection.
THE WITNESS: I don't know.
BY MR. O'CONNOR:
Q. Is there a particular process that

DEA follows when setting its aggregate production quota for opioid products?
A. Yes.
Q. Could you describe that process?
A. It takes into account all of the steps that you just mentioned earlier.
Q. And who is involved at DEA in the process?
A. There are various people in different sections involved in the process.
Q. Can you give me some examples?
A. The quota section is involved, the reg writing group is involved, chief counsel is involved. It's various sections within the agency.
Q. Through that process, the agency determines an aggregate production quota for various individual classes of controlled substances, correct?
A. In Schedule I and II, yes.
Q. And those proposed for a proposal for those quotas are then published in the Federal Register; is that correct?
A. Yes.
Q. Before they are published in the

Federal Register, who at DEA needs to approve the aggregate production quota numbers?
A. I don't understand your question.
Q. Before the aggregate production quota numbers are published in the Federal Register, does someone at the agency have to approve those numbers?
A. The final approval of those numbers is by the person who signs the Federal Register.
Q. And who is that in the case of aggregate production quotas?
A. It would be the administrator or active administrator or the deputy administrator depending on who is in charge at that time.
Q. Okay. Before the aggregate production quota numbers go to any of the individuals you just mentioned, are there others at DEA that have to sign off first?
A. Yes.
Q. Okay. Who are those people that need to sign off first?
A. I don't know the exact list of people who sign off, but it would be the head

of diversion, as well as whoever is in the chain between that person and the administrator.
Q. Okay. When you were --
MR. CHANDLER: I'm sorry, I will jump in here. Stacy prepared a list of people in the approval chain going back to at least 2011, so I think that would be a good time to work from this, so if you want to testify from that, and we have a copy for you all.
MR. O'CONNOR: Thank you. Appreciate that.
BY MR. O'CONNOR:
Q. And Ms. Harper-Avilla, have you reviewed this document before?
A. Yes.
Q. And is all the information contained in it accurate?
A. Yes.
Q. Okay.
MR. O'CONNOR: I'm going to mark this Exhibit 4.
(Deposition Exhibit 4 was marked for identification.)
BY MR. O'CONNOR:

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Q. Just so I understand, this document lists the individuals at DEA who were required to review and approve aggregate production quota before it was published in the Federal Register; is that correct?
A. Yes.
Q. And while you were unit chief and then section chief, did you also have to approve the quota numbers before they were published in the Federal Register?
A. Yes.
Q. During any year in which you approved those numbers, did you feel that they did not reflect the legitimate medical, scientific and industrial needs of the United States?
MR. CHANDLER: Objection. Scope.
THE WITNESS: No.
BY MR. O'CONNOR:
Q. After the proposed aggregate production quotas are published in the Federal Register, do members of the public have an opportunity to comment on them?
A. Yes.
Q. So if someone felt that the

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aggregate production quotas were too high, for example, would they have an opportunity to submit comments to the DEA reflecting that view?
A. Yes.
Q. If the DEA received any comments regarding the aggregate production quota, would it take them into account when deciding the final aggregate production quota numbers?
A. Can I have the question again.
Q. Sure. If the DEA received any comments regarding the aggregate production quota, would it take them into account when deciding the final aggregate production quota numbers?
A. Yes.
Q. Is there a process in place at DEA for determining individual manufacturing quotas?
A. Yes.
Q. What is that process?
A. I don't have it detailed. It's in the C.F.R., but basically, a bulk manufacturer would be required to provide information regarding why they needed that quota.

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Q. And who considers that request within the agency?
A. The UN reporting section does.
Q. What factors does DEA take into account when deciding whether to grant or how much to grant with respect to individual manufacturing quota?
A. The factors are laid out in the regulation and we consider those factors.
Q. Okay. As you sit here today, do you recall what those factors are?
A. I have the C.F.R. with me, but I don't remember them verbatim.
Q. Fair enough. Fair enough. Let's take a look at -- see if we can help.
MR. O'CONNOR: I'm going to mark this as Exhibit 5.
(Deposition Exhibit 5 was marked for identification.)
BY MR. O'CONNOR:
Q. Was this the regulation that you were thinking of a minute ago?
A. Yes.
Q. All right. So I am looking at Section 1303.23(a).

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Is that the section that describes the factors DEA considers when determining individual manufacturing quotas?
A. Yes.
Q. Okay. And in Subsection 2, it says that the individual manufacturing quota can be adjusted "by any other factors which the administrator deems relevant."
Is that your understanding of the regulation?
MR. CHANDLER: Objection. Vague.
THE WITNESS: I don't understand your question.
BY MR. O'CONNOR:
Q. Fair enough. The DEA is permitted to adjust individual manufacturing quotas based on any factor the administrator deems relevant, correct?
MR. ELSNER: Objection.
THE WITNESS: Yes.
BY MR. O'CONNOR:
Q. Among those factors listed here is the extent of any diversion of the controlled substance.
Do you see that?

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A. In Subsection 2?
Q. Yes.
MR. CHANDLER: Are we looking at (a)(2) or (b)(2)?
MR. O'CONNOR: (a)(2).
THE WITNESS: I do not.
BY MR. O'CONNOR:
Q. So does the DEA consider, in setting individual manufacturing quotas, the extent of diversion of a particular controlled substance?
A. It depends on the manufacturer.
Q. What do you mean by that?
A. The CSA and these implemented regs were written at a time when most manufacturers were vertically integrated from top to bottom and put to actual patient pill form, but currently, that is not the case for most of the manufactures who are applying to be a bulk manufacturer. They are applying to provide material to a second manufacturer who is then authorized to do dosage form to the patient, so there is a disconnect apparently between how these regs were written and actual business practices today. If a manufacturer is vertically integrated, then yes, it would be

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considered.
Q. Okay. To the extent a manufacturer is not vertically integrated, would the DEA still consider the extent of diversion of a particular controlled substance when determining the appropriate individual manufacturing quota?
A. Yes.
Q. In determining the individual manufacturing quota, would the DEA also consider whether the manufacturer was complying with the Controlled Substances Act?
A. I don't understand your question.
Q. If the DEA believed a manufacturer was not complying with the Controlled Substances Act, would it grant that manufacturer an individual manufacturing quota?
MR. ELSNER: Objection.
THE WITNESS: I still don't understand your question.
BY MR. O'CONNOR:
Q. In the course of the approval process for an individual manufacturing quota, if it came to your attention that the requester was not complying with the Controlled

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Substances Act, would you grant that quota request?
MR. ELSNER: Objection.
MR. CHANDLER: Objection. Vague.
THE WITNESS: The Controlled Substances Act is a multipiece document and it would depend on what violation they are supposedly accused of.
BY MR. O'CONNOR:
Q. If the DEA believed that a manufacturer did not have effective controls against diversion in place, would it grant that manufacturer an individual manufacturing quota?
MR. CHANDLER: Objection. Vague.
MR. ELSNER: Objection.
THE WITNESS: Can I have the question again.
BY MR. O'CONNOR:
Q. Sure. If the DEA believed that a manufacturer did not have effective controls against diversion in place, would it grant that manufacturer an individual manufacturing quota?
MR. ELSNER: Objection.
MR. CHANDLER: Same objection.
THE WITNESS: The DEA has to act on

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more than belief. As a government entity, it is fact-based, fact-driven.
BY MR. O'CONNOR:
Q. If the DEA was aware of any facts that a manufacturer was not maintaining effective controls against diversion, would it grant that manufacturer an individual manufacturing quota?
MR. ELSNER: Objection.
MR. CHANDLER: Objection. Form.
THE WITNESS: Each manufacturer is allowed due process until the fact is proven with certainty.
BY MR. O'CONNOR:
Q. So it's your testimony here today, that if you were aware that a manufacturer was not maintaining effective controls against diversion, you would still grant that manufacturer an individual manufacturing quota?
MR. ELSNER: Objection.
MR. CHANDLER: Objection. Vague. Form generally.
THE WITNESS: If the DEA had knowledge, it would investigate it, and that's what would occur in between whether a quota was

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granted or not.
BY MR. O'CONNOR:
Q. And if that investigation determined that the manufacturer was not maintaining effective controls against diversion, the DEA would not grant it a manufacturing quota, correct?
MR. ELSNER: Objection.
MR. CHANDLER: Objection. Form.
THE WITNESS: If the DEA had evidence and the due process was completed, the manufacturer would not be granted quota.
BY MR. O'CONNOR:
Q. Okay. I want to turn to procurement quota now.
What does procurement quota refer to?
A. Procurement quota is the quota granted for a manufacturer to receive or procure aggregate production -- active pharmaceutical ingredients, API, from a bulk manufacturer, so this is where I talk about the fact that the manufacturing process is not vertically integrated and bulk manufacturers will sell to dosage form manufacturers who are

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not the same company. Therefore, a procurement quota is necessary.
Q. Fair to say that procurement quota is what allows a manufacturer to buy the raw material that it needs to produce a dosage product?
A. Correct.
Q. Okay. Is there a process in place at DEA for considering and approving procurement quotas?
A. Yes.
Q. What is that process?
A. It depends on the manufacturer's business practice and it's written out in the C.F.R. under procurement quota.
Q. Okay.
MR. O'CONNOR: We will mark this Exhibit 6.
(Deposition Exhibit 6 was marked for identification.)
BY MR. O'CONNOR:
Q. Are you familiar with this regulation?
A. Yes.
Q. And it's the regulation that governs

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the allocation of procurement quota, correct?
MR. CHANDLER: Objection. Vague as to time.
BY MR. O'CONNOR:
Q. You can answer the question.
A. It does, after the effective date.
Q. Fair enough. And to your knowledge, has this regulation changed significantly in the last 20 years?
MR. CHANDLER: Objection. Vague. Scope.
MR. ELSNER: Objection.
THE WITNESS: It changed last year.
BY MR. O'CONNOR:
Q. Do you know which -- in what way it changed?
MR. ELSNER: Objection.
BY MR. O'CONNOR:
Q. Strike that.
Let's move on. Do you agree with the statement in Subsection A that one of the purposes of the procurement quota is to ensure an adequate and uninterrupted supply of basic classes of controlled substances?
MR. CHANDLER: Objection. Scope.

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THE WITNESS: That's what is written there, yes.
BY MR. O'CONNOR:
Q. Okay. And in setting procurement quotas, do you consider the need to ensure an adequate and uninterrupted supply of basic classes of controlled substances?
A. Yes.
Q. How does the DEA determine how much procurement quota to allocate to a particular manufacturer?
A. It depends on the manufacturer's business activity on what considerations are taken into account.
Q. What are some of the considerations that might be taken into account?
A. FDA approval.
Q. Okay.
A. Manufacturing yields and losses.
Q. Are there any other factors that DEA takes into account when considering how much procurement quota to grant?
A. Yes.
Q. What are those factors?
A. Basic market share, FDA recalls.

Q. Okay. Are there any other factors, other than those we just discussed, that the DEA considers when setting procurement quota?
A. Known cases against a manufacturer.
Q. What do you mean by "known cases?"
A. We can't consider something we don't know. If there is unfortunately a case going on from another part of DEA that we are not apprised of, then we cannot consider it.
Q. What do you mean by "a case?"
A. An investigation.
Q. If DEA had reason to believe that a manufacturer was causing controlled substances to be diverted, would it grant that manufacturer a procurement quota?
MR. CHANDLER: Objection.
THE WITNESS: It would be turned over to the field investigators to determine.
BY MR. O'CONNOR:
Q. And if those field investigators determined that the manufacturer was causing controlled substances to be diverted, would it grant that manufacturer a procurement quota?
MR. CHANDLER: Objection. Vague. Incomplete hypothetical.

MR. ELSNER: Objection.
THE WITNESS: The manufacturer would still end up going through due process.
BY MR. O'CONNOR:
Q. But at the end of the day, if DEA found that that manufacturer was diverting controlled substances or causing them to be diverted, DEA would not give them a procurement quota, correct?
MR. ELSNER: Objection.
MR. CHANDLER: Objection. Vague. Incomplete hypothetical.
THE WITNESS: At the end of due process, if the manufacturer was found to be in violation, then there would be no quota, but during the due process, it is open.
MR. O'CONNOR: We have gone about another hour. Should we take a break?
MR. CHANDLER: Okay.
THE VIDEOGRAPHER: We are going off the record. This is the end of Media Unit No. 2. The time is 11:58.
(A short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. This is the beginning of Media

Unit No. 3. The time is 1:07.
You may proceed, Counsel.
BY MR. O'CONNOR:
Q. Welcome back.
A. Thank you.
MR. O'CONNOR: I'm going to mark two documents here as Exhibits 7 and 8.
(Deposition Exhibit 7 was marked for identification.)
(Deposition Exhibit 8 was marked for identification.)
BY MR. O'CONNOR:
Q. These are documents that appeared on DEA's website.
A. Okay.
MR. CHANDLER: Just so we are clear, Document 7 is the one updated January 13, 2010; is that right?
MR. O'CONNOR: That's correct.
MR. CHANDLER: And 8 is the January 22nd.
MR. O'CONNOR: That's right.
BY MR. O'CONNOR:
Q. Starting with No. 7, which reflects the aggregate production quota history for

selective substances between 2000 and 2010.
Do you see that?
A. Yes.
Q. Do you recognize this chart?
A. I recognize the format of the chart, yes.
Q. Do you agree that it reflects the aggregate production quota history for the substances listed here on the left?
MR. ELSNER: Objection.
THE WITNESS: With the exception of 2010, it reflects the aggregate production quota as finalized from 2000 to 2009.
BY MR. O'CONNOR:
Q. Okay. And with respect to 2010, what does it reflect?
A. It would reflect the established.
Q. And is it fair to state the established quota might change over the course of the year?
A. Correct.
Q. Let's look at No. 8, Exhibit 8.
A. Yes.
Q. And do you agree that this reflects the aggregate production quota history for the

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substances listed on the left between the years 2009 through at least 2018?
A. The final aggregate production quota, yes.
Q. And I want to direct your attention on Exhibit 7 to the lines that say: "Oxycodone (sale) and oxycodone (CONV)."
What does oxycodone (sale) mean?
A. That that is the aggregate production quota set for oxycodone that will go to dosage form manufacturers.
Q. Okay. And what does oxycodone (CONV) mean?
A. So CONV stands for conversion and that is the amount of oxycodone that will be converted to a different substance.
Q. And you agree that the numbers listed to the right of oxycodone (sale) reflect the final aggregate production quota for the years listed in the column headings?
MR. CHANDLER: Objection. Mischaracterizes prior testimony.
THE WITNESS: For 2000 through 2009, yes.
BY MR. O'CONNOR:

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Q. Okay. So just to make sure I am reading this correctly, if we look in the column 2008, the number is for oxycodone (sale) 70,000.
What does that 70,000 represent?
A. That 70,000 represents the DEA's estimated final number of the amount of oxycodone for sale that may be required to fulfill legitimate, scientific, medical, research, industrial needs, export as well as inventory requirements.
Q. Okay. And in coming to that number, did DEA take into account the factors that it was required to consider under the Controlled Substances Act?
MR. ELSNER: Objection.
THE WITNESS: Yes.
BY MR. O'CONNOR:
Q. And in coming to that number, did DEA consider the factors it was required to under the regulation related to aggregate production quota?
A. Yes.
Q. And with respect to the numbers listed for the other substances here, did the

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DEA consider all of the factors it was required to consider under the Controlled Substances Act in determining those numbers?
MR. CHANDLER: Objection. Scope.
THE WITNESS: So far as the factors related to that substance, then yes.
BY MR. O'CONNOR:
Q. Just to address counsel's objection to scope, with respect to all the numbers listed in Exhibits 7 and 8 that are opioids, did the DEA consider all of the factors that it was required to consider by the Controlled Substances Act?
A. Where appropriate, yes.
Q. Were there any instances in which DEA did not consider factors it was required to consider under the Controlled Substances Act?
A. If there was no data for it, then no, we could not consider it.
Q. Are there any substances for which there was no data to consider the factors the DEA was required to consider?
MR. ELSNER: Objection.
MR. CHANDLER: Objection.
BY MR. O'CONNOR:

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Q. You can answer.
A. Yes.
Q. And which were those?
A. Alfentanil is only for export so there is not -- the other factors are missing when we do the request.
Q. So with respect to codeine -- and just to be clear, you said Alfentanil, correct?
A. Correct.
Q. I want to make sure the court reporter has that. Thank you.
With respect to codeine, fentanyl, hydromorphone, levorphanol, methadone, morphine, opium, oxycodone, hydromorphone and sufentanil, are you aware of any year in which the data DEA was required to consider to determine the aggregate production quota was not available?
A. That list that you mentioned is rather long and I don't remember all the substances so where the substances had data for every single factor, those factors were considered. If there was a place where FDA did not approve or it was not marketed in the U.S., then it could not be considered.

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Q. With the exception of Alfentanil, which you already mentioned, are there any other products for which DEA did not have the data necessary for it to consider the factors that it's required by statute and regulation to consider in establishing the aggregate production quota?
MR. CHANDLER: Objection.
THE WITNESS: There would be places -- there would be substances where DEA could not have full data, yes.
BY MR. O'CONNOR:
Q. And which are those substances?
A. Opium.
Q. Okay. Are there any other substances for which DEA did not have the data it needed to determine aggregate production quota?
MR. CHANDLER: Objection.
THE WITNESS: Yes, there's other places.
BY MR. O'CONNOR:
Q. And what are those?
A. Methadone.
Q. Okay. What information was lacking

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with respect to Methadone?
MR. CHANDLER: Objection.
THE WITNESS: Methadone is used in narcotics treatment facilities and therefore, it is not always recorded accurately. Therefore, actual usage is not always captured correctly.
BY MR. O'CONNOR:
Q. Okay. So for oxycodone, in particular, for each of the years listed here, did DEA consider the factors it was required by statute and regulation to consider in setting the aggregate production quota?
A. Yes, where data is available, yes.
Q. Were there any years during which data was not available for oxycodone?
MR. ELSNER: Objection.
THE WITNESS: There were years where manufacturers did not submit complete and timely information in order for us to do our work.
BY MR. O'CONNOR:
Q. When DEA granted the quota for oxycodone during those years, on what information did it rely?

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MR. CHANDLER: Objection.
THE WITNESS: I don't understand the question.
BY MR. O'CONNOR:
Q. If you didn't have data from manufacturers, how did you make that decision?
A. For which?
Q. Oxycodone.
A. For which? Our aggregate production quota?
Q. Yes.
A. DEA made the decision based on manufacturing data, FDA data as well as other information as required in the CSA. However, DEA bills each year separately so if a manufacturer pulled out of the market, they would not submit that data. However, a new manufacturer may come into the market and have a different weighted value for the market at that time.
Q. Would you agree that with respect to aggregate production quota for oxycodone, that DEA considered the factors it was legally required to consider?
A. Yes.

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Q. Okay. With respect to Hydromorphone, in each of the years listed here, do you agree that with respect to aggregate production quota, DEA considered the factors it was legally required to consider?
A. Yes.
Q. With respect to Hydromorphone -- sorry, strike that.
With respect to Hydrocodone, in each of the years listed, do you agree that with respect to aggregate production quota, DEA considered the factors it was legally required to consider?
A. Yes.
Q. With respect to oxymorphone, in setting the aggregate production quota in each of the years listed, do you agree that DEA considered the factors it was legally required to consider?
A. Yes.
Q. With respect to fentanyl, in setting the aggregate production quota for the years listed here, did DEA consider the factors it was legally required to consider?
A. Yes.

Q. With respect to morphine, in setting the aggregate production quota, did DEA consider all of the factors it was legally required to consider?
A. Yes.
Q. As a representative of DEA sitting here today, do you believe the DEA is responsible for the numbers that appear on this sheet?
MR. ELSNER: Objection.
MR. CHANDLER: Objection. Scope. Vague.
THE WITNESS: The DEA is known to put the numbers out, yes, correct.
BY MR. O'CONNOR:
Q. So you would agree that DEA is responsible for the aggregate production quota set each year for these products?
MR. CHANDLER: Objection. Scope. Vague.
MR. ELSNER: Objection.
THE WITNESS: DEA is required to publish the value, correct, yes.
BY MR. O'CONNOR:
Q. DEA also determines the value of the

quota for each of these substances, correct?
MR. CHANDLER: Objection.
MR. ELSNER: Objection.
THE WITNESS: DEA is required to provide an estimated value for these substances.
BY MR. O'CONNOR:
Q. And the numbers that are ultimately published as the aggregate production quota for each of these substances are determined by DEA, correct?
MR. CHANDLER: Objection.
THE WITNESS: With assistance from other agencies, yes.
BY MR. O'CONNOR:
Q. Does DEA set an aggregate production quota for the total amount of Hydrocodone that can be manufactured in a given year?
A. Yes.
Q. So when Hydrocodone is used in combination product, like Vicodin, the amount of Hydrocodone used counts against the quota amount, correct?
A. Yes.
Q. And that was true when Hydrocodone

combination products were listed as Schedule III controlled substances, correct?
A Yes
MR O'CONNOR: Can we take a short break
THE VIDEOGRAPHER: We are going off the record The time is 1:25
(A short recess was taken)
THE VIDEOGRAPHER: We are back on the record The time is 1:41
You may proceed, Counsel
EXAMINATION BY COUNSEL FOR DEFENDANT McKESSON
BY MR EPPICH:
Q Ms Harper-Avilla, my name is Chris Eppich I'm from the law firm of Covington & Burling and I represent McKesson in this matter
Are you familiar with the distributor defendants in this case?
A I know of McKesson
Q McKesson and AmerisourceBergen and Cardinal Health?
A Yes
Q Those are -- I represent those folks today for this portion of your testimony

Let me -- let me pick up where Mr. O'Connor just left off. He asked you a question referring to Exhibit 7 and 8.
He asked you, and I will just read it right from the record. He said: "So just to make sure I am reading this correctly, if we look at the column 2008, the number for oxycodone sales 70,000, what does that 70,000 represent?"
And your testimony, ma'am, your answer: "That 70,000 represents the DEA's estimated final number of the amount of oxycodone for sale that may be required to fulfill legitimate, scientific, medical research, industrial needs as well as inventory requirements."
Do you remember providing that testimony, ma'am?
A. Yes.
Q. And would your answer be the same for every year reflected on Exhibit 7 and 8?
MR. CHANDLER: Objection. Vague.
THE WITNESS: It would -- it would be for legitimate medical needs, scientific research, industrial, export as well as

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inventory needs, yes, and then the manufacturing losses that are necessary to make those final figures.

BY MR. EPPICH:

Q. Thank you. And is it also true for every opioid that is listed on Exhibit 7 and 8?

MR. CHANDLER: Objection. Vague.

THE WITNESS: It would -- it would work for those that are -- have FDA-approved products. Those that do not, no.

BY MR. EPPICH:

Q. And which ones have FDA-approved products, ma'am?

A. That, I can't -- I couldn't cite all of those.

Q. Well, oxycodone is one of them, correct?

A. Correct.

Q. Hydrocodone?

A. Yes.

Q. Hydromorphone?

A. Yes.

Q. Morphine?

A. Yes.

Q. Fentanyl?

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A. Yes.

Q. Do any others come to mind after we just reviewed five? Oxymorphone, for example?

A. Correct.

Q. Oxy -- I will leave it at that.

Now, Mr. O'Connor asked you several questions about the information DEA considers in setting the aggregate production quota.

Do you remember that testimony today?

A. Yes.

Q. You testified that DEA sets each of these quotas annually, correct?

A. Correct.

Q. Now, do wholesale manufacturers such as McKesson, Cardinal and AmerisourceBergen provide any information to DEA that is used to set those quotas?

MR. ELSNER: Objection.

THE WITNESS: Quotas are not related to distributors, so no.

BY MR. EPPICH:

Q. And pharmacy chains, such as CVS, Walgreens, Rite Aid, Walmart, Giant Eagle, HBC, they also don't provide any information to DEA

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that is used to set the quotas, correct?

MR. ELSNER: Objection.

MR. CHANDLER: Objection.

THE WITNESS: The list of companies you just provided do not receive quota and therefore, are not considered for aggregate production quotas.

BY MR. EPPICH:

Q. DEA does not consult with wholesale distributors, such as McKesson, Cardinal and AmerisourceBergen when DEA sets the quotas for controlled substances, correct?

A. Correct.

Q. And DEA does not consult with pharmacy chains, such as CVS, Walgreens, Rite Aid, Walmart, Giant Eagle, HBC, when DEA sets quotas for controlled substances?

A. Correct.

MR. CHANDLER: Objection.

BY MR. EPPICH:

Q. Wholesale distributors, such as McKesson, Cardinal, AmerisourceBergen, they do not apply for DEA -- to DEA for quotas, do they?

MR. CHANDLER: Objection.

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THE WITNESS: Correct.

BY MR. EPPICH:

Q. And pharmacy chains, such as CVS, Walgreens, Rite Aid, Walmart, Giant Eagle, HBC, they also do not apply to DEA for quotas, correct?

MR. CHANDLER: Objection. Scope.

MR. ELSNER: Objection.

THE WITNESS: Correct.

BY MR. EPPICH:

Q. Now, DEA is required by law to establish aggregate production quotas for certain controlled substances, correct?

A. Correct.

Q. There are a number of statutes and regulations that govern the process DEA must follow and the considerations DEA must consider in establishing quotas for controlled substances?

MR. CHANDLER: Objection.

THE WITNESS: Correct.

BY MR. EPPICH:

Q. And DEA endeavors to comply with these statutes and regulations governing the establishment of quotas for controlled

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substances, correct?
A. Correct.
Q. In following these statute and regulations, the aggregated production quota reflects the estimated medical, scientific research and industrial needs of the United States, correct?
A. Along with export requirements and inventory requirements and manufacturing yield and losses counted in, yes.
Q. The aggregate production quota is the maximum amount of a controlled substance that can be manufactured and distributed in a year, correct?
A. It's the maximum amount that can be manufactured within a year.
Q. In setting the quota, the aggregate production quota for a prescription opioid, DEA understands that pharmaceutical manufacturers may manufacture, wholesale distributors may distribute, and pharmacies may dispense to patients up to the amount the DEA allowed, correct?
MR. CHANDLER: Objection.
THE WITNESS: I don't understand

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your question.
BY MR. EPPICH:
Q. Well, I am just asking. If DEA sets an aggregate production quota, DEA understands that the manufacturers may manufacturer up to that limit, correct?
MR. CHANDLER: Objection.
THE WITNESS: I don't understand your question.
BY MR. EPPICH:
Q. Let me try again. I will try and make it more clear, ma'am.
In setting the quota --
A. The aggregate production quota?
Q. The aggregate production quota, the DEA understands that pharmaceutical manufacturers, they are going to manufacture enough drugs to supply up to that quota amount, correct?
MR. CHANDLER: Objection.
THE WITNESS: No. So the manufacturer, if they are granted an individual quota, will manufacture up to that individual quota, not up to the APQ. The APQ is the aggregate of all manufacturers and it's the

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estimated need, not the granted need.
BY MR. EPPICH:
Q. And so the aggregate production quota is the total of all the individual manufactured quotas that DEA expect manufacturers to manufacture that year?
MR. CHANDLER: Objection.
MR. ELSNER: Objection.
THE WITNESS: It's an estimate.
BY MR. EPPICH:
Q. But it's true that DEA understands that ultimately, pharmacies may dispense to patients across this country, an amount of the controlled substance that is set by the aggregate production quota, correct?
MR. ELSNER: Objection.
MR. CHANDLER: Objection.
THE WITNESS: A pharmacy may dispense an amount needed for legitimate patient need.
BY MR. EPPICH:
Q. If the DEA increases the aggregate production quota for prescription opioids, DEA understands that it is allowing more opioids in the communities, correct?

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MR. CHANDLER: Objection.
MR. ELSNER: Objection.
THE WITNESS: The reason for an increase in an aggregate production quota is not automatically equated with what goes out to the community itself. It could be used for scientific and research needs which are different and separate from what is seen in -- for patient needs.
BY MR. EPPICH:
Q. How much of the aggregate production quota goes to patient needs on a given year?
MR. CHANDLER: Objection.
THE WITNESS: I don't know off the top of my head.
BY MR. EPPICH:
Q. But you would agree with me that each time the DEA increases that quota, the amount of -- in this case, prescription opioids that goes into the community increases?
MR. CHANDLER: Objection.
MR. ELSNER: Objection.
THE WITNESS: I would not -- I would suggest that it would go towards a scientific or research need perhaps or export need which

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has nothing to do with domestic communities.
BY MR. EPPICH:
Q. Do you know or are you guessing when you provide that response?
MR. CHANDLER: Objection.
MR. ELSNER: Objection.
THE WITNESS: It would depend on the year.
BY MR. EPPICH:
Q. Do you agree that in setting the annual production quota, the DEA has the ability to control the amount of prescription opioids available to the public?
MR. CHANDLER: Objection.
THE WITNESS: I don't understand the question.
BY MR. EPPICH:
Q. Well, in setting the annual production quota, would you agree that DEA has the ability to control how much of a prescription opioid is available to the public?
MR. CHANDLER: Objection.
MR. ELSNER: Objection.
THE WITNESS: I would not.
BY MR. EPPICH:

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Q. Why not?
A. Because there are many other factors in between the number that is set and what goes out to the public.
Q. What are those factors?
A. Manufacturing losses and yield, FDA recalls, FDA changes in market practices, manufacturers losing contracts, among others.
Q. We talked a fair amount today about the process by which DEA sets the aggregate production quota.
Are there any DEA guides or manuals or written standards of operation procedures explaining the process how DEA sets the annual production quota?
A. Yes.
Q. And what are those documents called?
A. SOPs, standard operating procedures.
Q. Is there a specific one that you have in mind for setting the aggregate production quota?
A. Not one in mind definitely.
Q. There are multiple?
A. They -- the document exists.
Q. Where would I find that document?

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A. It is not for public consumption.
Q. Where do you find that document?
MR. ELSNER: Objection.
THE WITNESS: Within DEA's internal control.
BY MR. EPPICH:
Q. Is there a server that it's stored on, is there a bookshelf that it's stored on?
A. More than likely a server.
Q. You access it electronically is what you are saying?
A. It would be.
Q. Do you access it?
A. I do not because it's the same as the regs in the statute, and therefore, if you can read the regs in the statute, for the most part, the information is there, as well as the FDA letter that comes in.
Q. Does your team rely on these standard operating procedures?
A. Yes.
Q. And where do they go to look for it? Do they know the name of this document?
A. I'm sure they do.
Q. But you do not sitting here today?

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A. It is just called SOPs, quota SOPs.
Q. Thank you. Earlier today, you testified that you met with Mr. Joe Rannazzisi and Dr. Chris Sannerud, correct?
MR. CHANDLER: Objection.
THE WITNESS: Correct.
BY MR. EPPICH:
Q. That was in preparation for your deposition today?
A. Yes.
Q. And before your preparation sessions with your counsel, when was the last time that you communicated with Mr. Rannazzisi?
A. 2015.
Q. And when was the last time that you communicated with Ms. Sannerud?
A. March perhaps.
Q. In your communications with Ms. Sannerud, were those in relation to preparing for the deposition today?
A. Not all of those, no.
Q. What did you discuss with Ms. Sannerud during those conversations?
A. The ones in March?
Q. Yes, ma'am.

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A. The birth of her grandson.
Q. You're friends?
A. We've worked together for a long time.
Q. Are you aware that Mr. Rannazzisi has been subpoenaed to testify in this case?
A. Yes.
Q. When did you become aware of that?
MR. CHANDLER: Objection. Scope.
THE WITNESS: Probably last year sometime.
BY MR. EPPICH:
Q. Are you aware that he will be deposed in the coming weeks?
MR. CHANDLER: Objection. Scope.
THE WITNESS: No.
BY MR. EPPICH:
Q. Are you aware that defendants have requested the deposition of Ms. Sannerud in this litigation?
MR. CHANDLER: Objection. Scope.
THE WITNESS: Yes.
BY MR. EPPICH:
Q. When did you -- when did you become aware of that?

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MR. CHANDLER: Same objection.
THE WITNESS: Last year sometime.
BY MR. EPPICH:
Q. Now, earlier today, you were asked who was present during your preparation sessions.
Do you remember that?
A. Yes.
Q. And I believe you responded that counsel for the DOJ was there with you?
A. Yes.
Q. Were there any other -- were there any other people present, other than yourself, Mr. Rannazzisi, Ms. Sannerud and counsel for DOJ present during those discussions?
MR. CHANDLER: Objection. Mischaracterizes prior testimony.
THE WITNESS: Mr. Rannazzisi and I were not in the same room so I don't know who was on the other end of the phone with him.
BY MR. EPPICH:
Q. Was there someone else on the phone with him?
A. I don't know. I can't answer what I could not see.

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Q. How many -- how many phone calls did you have with Mr. Rannazzisi in preparation for today's deposition?
A. One.
Q. And how long did that conversation last?
A. Approximately an hour.
Q. I would like to return to Exhibit 4.
Exhibit 4 is the document that I understand you or your counsel prepared titled: "APQ Review and Approval."
A. Yes.
Q. Did you prepare this document, ma'am?
A. I assisted in it.
Q. Now, the document starts in 2011, correct?
A. Correct.
Q. And it identifies in July 2011 -- Joseph T. Rannazzisi is the first name on the list?
A. Yes.
Q. Does that -- does that indicate that Mr. Rannazzisi was the final approver of the proposed adjustments for 2011?

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A. No.
Q. Who would be the final approver in this list?
A. Michelle Leonard.
Q. And so does the list -- does the way your approval process works, Mr. Rannazzisi would approve it, Mr. Ryan would then approve it, Mr. Mullinax -- or Ms. Mullinax would approve it, Mr. Tuggle would then approve it and then Ms. Leonard would approve it? Is that -- is that how it works?
A. Yes.
Q. And is that process the same for each -- each of these tables that you prepared for us for each of the years in Exhibit No. 4?
MR. CHANDLER: Objection.
THE WITNESS: It does not seem to be in that same order on all of these.
BY MR. EPPICH:
Q. Okay. For 2011, we are looking at 2011 in particular, Mr. Rannazzisi would have approved the aggregate production quota amounts for each of the classes in 2011, correct?
MR. ELSNER: Objection.
THE WITNESS: Yes.

BY MR. EPPICH:
Q. And the same is true for each year that we see Mr. Rannazzisi's name in Exhibit 4; is that correct?
A. Yes.
Q. Now, Mr. Rannazzisi joined the office of diversion control before 2011, correct?
A. Yes.
Q. And he had a role in his approval or authorization of the aggregate production quota before 2011?
A. Yes.
Q. And that would be true for his tenure as the deputy assistant administrator for the office of diversion control, correct?
A. Correct.
MR. EPPICH: Let's take a short break.
THE VIDEOGRAPHER: We are going off the record. This is the end of Media Unit No. 3. The time is 2:02.
(A short recess was taken.)
THE VIDEOGRAPHER: We are going back on the record. This is the start of Media Unit

No. 4. The time is 2:12.
You may proceed, Counsel.
BY MR. EPPICH:
Q. Ms. Harper-Avilla, you testified today as DEA's 30(b)(6) witness for almost three hours.
Has any of your testimony been informed by your discussions with Mr. Rannazzisi and Ms. Sannerud?
MR. CHANDLER: Objection.
MR. ELSNER: Objection.
THE WITNESS: They have clarified issues that I may have had in preparation, but -- they clarified issues I had in preparation.
BY MR. EPPICH:
Q. And what issues were clarified, ma'am?
A. Whether certain documents existed for me to review or not.
Q. Which documents were those?
A. Documents related to setting the APQ.
Q. And what information specifically did you discuss with Mr. Rannazzisi that clarified issues for you?

MR. CHANDLER: Objection.
THE WITNESS: That in 2013, there was a 25 percent buffer added to the APQ for FDA-approved products.
BY MR. EPPICH:
Q. And what did he mention about that?
A. That there were meetings held between DEA and the bulk manufacturers regarding that issue.
Q. Anything else?
A. No. That was a point of clarification for me.
Q. Were there any other points of clarification Mr. Rannazzisi made to you?
A. For that? No.
Q. For any other topic, ma'am.
A. Yes.
Q. What did he say?
A. That it was a point of clarification on the section's ability to speak to registrants.
Q. And what was discussed?
A. The basis for that.
Q. What is the basis that he mentioned?
A. That there were former DEA personnel

who called various sections that were not related to the topic at hand.
Q. I am not understanding that.
A. There were former DEA personnel hired by manufacturers who would call a section in order to seek guidance or special favor that was not that section's ability or place.
Q. And which sections were those that were called?
A. It varied. It just was a matter of the fact that it was not -- they didn't call to do work for that section or with that section.
Q. Did you discuss any other points of clarification?
A. Yes.
Q. And what were those points?
A. DEA's investigation of the necessary -- the need to actually change the regulations.
Q. Which regulations?
A. The ones in the C.F.R. or quota.
Q. The regulations for quota?
A. Correct.
Q. And what did he say about the DEA's need to change the regulations for quota?
MR. CHANDLER: Objection. Scope.

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THE WITNESS: That the document had not been completed under him.
BY MR. EPPICH:
Q. What is the document, ma'am?
A. The proposed document, the proposed notice of proposed rule making had not occurred under him.
Q. Why was that important to him?
MR. CHANDLER: Objection.
THE WITNESS: It was not. It was just a point of clarification.
BY MR. EPPICH:
Q. And you are referring to the 2018 revision to the C.F.R.; is that correct?
MR. CHANDLER: Objection. Scope.
THE WITNESS: I think we were talking about things that he noticed needed to be changed within the C.F.R.
BY MR. EPPICH:
Q. Limited to the quota or other sections of the C.F.R.?
A. Not limited to quota.
Q. What other sections of the C.F.R. did Mr. Rannazzisi say should be changed?
A. We did not --

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MR. CHANDLER: Objection. Scope.
MR. ELSNER: Objection.
THE WITNESS: We didn't talk about it that much because it was not relevant to my preparation here.
BY MR. EPPICH:
Q. Did he mention any section at all?
MR. CHANDLER: Objection. Scope.
MR. ELSNER: Objection.
THE WITNESS: Just that he wanted to make other changes.
BY MR. EPPICH:
Q. But he did not mention a specific section that he wanted to change?
MR. CHANDLER: Objection. Scope.
MR. ELSNER: Objection.
THE WITNESS: He mentioned the fact that in the course of making changes for the quota, that there were other pieces that he had not gotten to.
BY MR. EPPICH:
Q. Were there any other points of clarification that you discussed with Mr. Rannazzisi in preparation for today's deposition?

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A. Yes.
Q. And what were those, ma'am?
A. In regard to pharmaceutical training seminars not going on through 2012 through 2015, being replaced instead by the pharmacy diversion awareness conferences.
Q. And what did you discuss on that topic?
A. Why -- we discussed whether or not -- why they both could not go on at the same time for each year.
Q. And why is that?
A. He felt that they overlapped and caused confusion and it would be better served to the agency if pharmaceutical -- that the pharmaceutical diversion awareness conference occurred instead, pharmacy diversion conference.
Q. Were there any other points of discussion or clarification that you discussed with him in preparation for today's deposition?
A. Yes.
Q. What were those points?
A. The change in signature authority on the individual quota letters.

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Q. And what did -- what did you discuss?
A. Clarification on the change that occurred.
Q. What was the change that occurred?
A. That quota letters went from being signed by the section chief to Mr. Rannazzisi.
Q. And when did that occur?
A. 2011.
Q. And these letters would be sent from the DEA to who?
A. Individual manufacturers.
Q. And was there an issue with the change in signatory?
MR. ELSNER: Objection.
MR. CHANDLER: Objection.
THE WITNESS: Not an issue with it. Just a time and make sure I am clear on the timing of when it occurred.
BY MR. EPPICH:
Q. And why would that be important?
MR. CHANDLER: Objection.
THE WITNESS: It was something that I did not know at the time. I did not recall correctly.

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BY MR. EPPICH:
Q. Were there any other points of clarification that you discussed with Mr. Rannazzisi during preparation sessions?
A. Not that I can recall at this time.
Q. Were there any points of clarification that you discussed with Ms. Sannerud?
A. Yes.
Q. And will you please explain those points to us?
MR. ELSNER: Objection.
THE WITNESS: It was the signature authority on the individual quota letters.
BY MR. EPPICH:
Q. Any other points of clarification?
A. And again, also the 25 percent increase put on to the APQ in 2013.
Q. And what did Ms. Sannerud say about the 25 percent increase put on to the APQ in 2013?
A. That she remembered that it went to only Schedule II substances.
Q. Anything else?
A. Just the time frame. That was it.

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Q. Did you discuss any other points of clarification with Ms. Sannerud in preparation for today's deposition?
A. Also the ability of the section to speak to registrants.
Q. And what did you discuss in that capacity?
A. Whether or not she could remember the time frame that it occurred in.
Q. Was MS. Sannerud present for the phone call with Mr. Rannazzisi?
A. No, she was not.
Q. These were separate phone calls?
A. Correct.
Q. Do you recall any other points of clarifications or topics that you discussed with Mr. Rannazzisi or Ms. Sannerud in preparation for today's deposition?
A. Not that I remember at this time, no.
Q. Did you discuss -- in your preparations for today's deposition, did you meet with any other members of the DEA?
A. Not that I recall.
MR. EPPICH: Let's go ahead and take a short break.
THE VIDEOGRAPHER: We are going off the record. The time is 2:24.
(A short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 2:37.
You may proceed, Counsel.
MR. EPPICH: Thank you for your time this afternoon, Ms. Harper-Avilla. We will reserve -- we will pass the witness and reserve our time for after your testimony.

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EXAMINATION BY COUNSEL FOR PLAINTIFFS
BY MR. ELSNER:
Q. Good afternoon.
A. Good afternoon.
Q. My name is Mike Elsner, I'm from the law firm Motley Rice and I represent the plaintiffs.
Does the Controlled Substances Act create a closed system for manufacturing, distributing and dispensing of controlled substances?
MR. CHANDLER: Objection. Scope.
THE WITNESS: It is supposed to do that.

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BY MR. ELSNER:
Q. And the DEA quota system is one element within that closed system, but it's not the only element; is that right?
A. Correct.
MR. CHANDLER: Objection. Scope.
BY MR. ELSNER:
Q. And do manufacturers and distributors of controlled substances like opioids have a responsibility to design a system to monitor and detect suspicious orders?
MR. CHANDLER: Objection. Scope.
MR. O'CONNOR: Objection.
THE WITNESS: Yes.
BY MR. ELSNER:
Q. And when suspicious orders are detected, do manufacturers and distributors have a duty to stop shipments of those orders and report those orders to the DEA?
MR. O'CONNOR: Objection. Scope.
MR. CHANDLER: I'm going to direct the witness not to answer, this is way outside the scope.
MR. ELSNER: I will tie it together quickly. I just want to give her a basic

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overview.
MR. CHANDLER: Can you explain, tied together on what basis? How does this tie together?
MR. ELSNER: You will see in the -- within the next few exhibits, I will show you. There's certain statements made by counsel in relationship to their responsibilities that don't exist because there is a quota system in place.
MR. CHANDLER: Are these questions really necessary to get there?
MR. ELSNER: I think it sets the stage for that, yes.
MR. O'CONNOR: Defendants object.
MR. CHANDLER: You can answer.
Do you need the question again?
THE WITNESS: I need the question again.
BY MR. ELSNER:
Q. Sure. When suspicious orders are detected, do manufacturers and distributors have a duty to stop shipments of those orders and report those suspicious orders to the DEA?
MR. O'CONNOR: Objection. Form.

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MR. CHANDLER: Objection. Scope.
You can answer.
THE WITNESS: I can't answer your question fully because that's not quite my area of expertise.
They definitely have a requirement to notify DEA.
BY MR. ELSNER:
Q. Okay. And you mentioned among the other factors that the DEA may consider is known diversion.
What did you mean by "known?"
A. Known would be something that had been adjudicated through the process.
Q. Is the responsibility for manufacturers and distributors to monitor for suspicious orders, stopping shipments of suspicious orders and inform the DEA, does that responsibility go away because there is a quota system in place by the DEA?
MR. O'CONNOR: Object to form and scope.
MR. CHANDLER: Objection. Scope.
MR. EPPICH: Objection. Foundation.
THE WITNESS: So the quota system is

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one portion of it, but it's incumbent upon the manufacturers and distributors and all of the participants within the quota system, within the controlled substance system, to do their part as per the regulations.
BY MR. ELSNER:
Q. Okay. So simply because there is a quota system in place, that doesn't excuse manufacturers and distributors from fulfilling their other obligations under the Controlled Substances Act; is that right?
MR. CHANDLER: Objection. Scope.
MR. O'CONNOR: Objection.
THE WITNESS: True.
MR. ELSNER: I want to mark Exhibit 9. This is a transcript.
(Deposition Exhibit 9 was marked for identification.)
BY MR. ELSNER:
Q. This is a transcript of a hearing in federal court in West Virginia and I want you to turn to Page 12 of the transcript and I want to review certain statements made in this transcript and see if you agree or disagree with them. Okay?

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Are you on Page 12?
A. Yes.
Q. Okay. At the very top of the page, it says: "We, the distributors, Your Honor, have absolutely no role in determining what the supply needs to be or in making a determination of what the demand is."
Do you see that?
A. Yes.
Q. Okay. And then if you go down, it says, after the dashes: "But the DEA every year sets the quota in this country for all Schedule I and Schedule II controlled substances that may be manufactured by the manufacturers and it sets that quota based on its evaluation of legitimate medical, scientific, industrial need for those substances."
Did I read that correctly?
A. Yes.
Q. Okay. The Court asks: "Is that a nationwide or is it a state specific? How is it broken down?"
Counsel for the distributors responds: "It's nationwide, Your Honor."

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The Court then asks -- if you are with me under where the Court -- it says: "Does that overcome the obligation of the distributors to be on the look out for suspicious high numbers of drugs going into specific areas?"

And the distributors lawyer says: "It does."

Is that statement accurate or inaccurate?

MR. EPPICH: Objection. Foundation. Form. Outside the scope.

MR. CHANDLER: Objection.

MR. O'CONNOR: Objection.

THE WITNESS: I'm not sure what the Court's question refers to at this point. I apologize.

BY MR. ELSNER:

Q. That's okay. The Court is asking whether that obviates the distributors need to be on the lookout for suspicious high numbers of drugs going into specific areas, and the distributors lawyer says that it does.

That statement is not true; is that right?

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MR. EPPICH: Objection. Foundation. Form. Scope.

MR. O'CONNOR: Objection. Scope.

MR. CHANDLER: This is well outside Topics 13 and 14 and outside the Touhy authorization.

Is this the big tie together that you promised a moment ago?

MR. ELSNER: I don't -- it is. I don't think that it is beyond the scope. The distributors have taken the responsibility before federal court that they are -- they are not obligated to fulfill their responsibilities because there is a quota system in place, and I want to make sure that that is inconsistent with the DEA's view of their responsibilities under the quota system.

MR. CHANDLER: Ms. Harper-Avilla has not been designated to testify about distributors' obligations related to reporting before the Court.

MR. ELSNER: No, I understand that, but she is responsible for the quota system and I think she's -- and I think whether that obviates the other responsibilities under the

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Controlled Substances Act is a fair inquiry.

MR. CHANDLER: Well, she is not going to testify or designated to testify about the establishment of quotas and the quota setting process, not other impacts it may have on other obligations of distributors or registrants.

MR. ELSNER: I think she is entitled to answer this question. She already answered the question essentially.

MR. O'CONNOR: The Touhy authorization is pretty limited in terms of the policies around the quota process and certain other topics that don't include obligations when there's suspicious monitoring.

MR. EPPICH: The distributors would also agree that this is well beyond the scope of the 30(b)(6) topics and any testimony that she may or may not provide would be personal testimony and no foundation has been established for any such testimony.

MR. RUIZ: The pharmacies would agree as well.

MR. CHANDLER: Yeah, I mean, Topic 3 is establishment of quotas for production of

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opioids in the United States, not secondary impacts or other obligations of registrants as a result of quotas.

MR. ELSNER: I understand. I think if I get an answer to this question, we can move on. I'm not going to belabor this.

MR. CHANDLER: This is the last question on this topic?

MR. ELSNER: Yes.

MR. CHANDLER: All right.

MR. EPPICH: We can still make our objection.

MR. CHANDLER: Our scope objection stands. I will allow the witness to answer in her personal capacity, not on behalf of the DEA.

You can answer if you know.

THE WITNESS: Can I have the question again?

BY MR. ELSNER:

Q. You may. The simple question is, is -- the Court asked counsel whether -- in the transcript, as a federal district court judge, whether the quota system overcame the obligations of the distributors to be on the

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lookout for suspicious high numbers of drugs going into specific areas, and counsel for the distributors said, it did. It overcame that responsibility.

And my question to you is: In your personal capacity, is that consistent or inconsistent with your understanding of the Controlled Substances Act?

MR. CHANDLER: I will renew my objection.

MR. O'CONNOR: Objection. Scope.

MR. EPPICH: Same objection. In addition to any -- to the extent it mischaracterizes the testimony on this document.

MS. McCLURE: Object to this line of questioning and the characterization of distributors and treating this argument as on behalf of the distributors as a whole.

MR. CHANDLER: You can answer if you know.

THE WITNESS: The quota system does not change the obligation of the distributors under this CSA.

BY MR. ELSNER:

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Q. Thank you. I want to turn to procurement quotas for a second, and in the procurement quota process, does the DEA approve in the quota system the dose of an opioid product that a manufacturer may make?

A. No.

MR. O'CONNOR: Objection to form.

BY MR. ELSNER:

Q. The DEA is really just authorizing a gross bulk amount of a controlled substance that a manufacturer may acquire to create a dose; is that right?

MR. O'CONNOR: Objection to form.

THE WITNESS: Correct.

BY MR. ELSNER:

Q. Okay. The DEA cannot issue a quota or a limit on the dosage units or number of specific opioid pills that a manufacturer can make, can they?

MR. MASTERS: Objection.

MR. CHANDLER: Objection.

THE WITNESS: The quota that is granted is by weight, kilogram, and in the sense, it will limit it that way, but it does not specific -- specify X number of tablets to

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be made.

BY MR. ELSNER:

Q. Okay. So can the DEA tell Purdue you cannot manufacture an 80 milligram OxyContin pill under the quota system?

MR. MASTERS: Objection.

MR. CHANDLER: Objection.

THE WITNESS: The DEA would be able to limit them only if it was not FDA-approved.

BY MR. ELSNER:

Q. Okay. But otherwise, they can -- but in any case, they cannot approve or disapprove of a particular dose of the use of the bulk substance, correct?

MR. CHANDLER: Objection.

MR. O'CONNOR: Object to form.

THE WITNESS: Correct.

BY MR. ELSNER:

Q. Would you agree with me that there are some types of drugs that are more abused than other drugs?

MR. CHANDLER: Objection. Scope.

MR. O'CONNOR: Objection.

MR. EPPICH: Objection. Vague.

THE WITNESS: I would not have a

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basis for that.

BY MR. ELSNER:

Q. Are you aware just in your personal capacity whether a red flag for diversion could be when a patient refers to an oxycodone pill as a blue or a panda bear or an octagon?

MS. McCLURE: Objection to form.

MR. EPPICH: Objection to form.

MR. O'CONNOR: Objection to form. Scope.

MR. CHANDLER: Objection to form. Scope.

THE WITNESS: I would think that that means that it's not for the intended purpose.

BY MR. ELSNER:

Q. Okay. And we all understand that there are certain drugs that are more subject to abuse than other drugs, but can the DEA through the quota system focus on creating a limit on the specific type of drug that is most subject to abuse?

MR. O'CONNOR: Object to form.

MR. CHANDLER: Objection. Scope.

MR. EPPICH: Objection. Foundation.

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THE WITNESS: I don't understand your question. I'm sorry.
BY MR. ELSNER:
Q. That's okay. My question is, is whether the DEA in the quota system could limit the authorization and just restrict authorization to the drugs that are most subject to abuse?
MR. CHANDLER: Objection. Scope.
MR. O'CONNOR: Objection.
THE WITNESS: Within the quota system, if it's an FDA-approved product without actual case data, then it would not be limited.
BY MR. ELSNER:
Q. Because what the DEA is looking at is the gross -- is the gross bulk amount of the substance, right?
They are not looking at the specific type of medicine or the specific dose, correct?
MR. O'CONNOR: Objection. Form.
MS. McCLURE: Objection. Form. Vague. Compound.
THE WITNESS: The DEA looks at bulk data.
BY MR. ELSNER:

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Q. Okay. The quota system run by the DEA is also national in scope; is that right?
A. Correct.
Q. Okay. It didn't -- it doesn't look at -- the quota system for the DEA doesn't look at how many pills a distributor like AmerisourceBergen or Cardinal could distribute to a particular pharmacy in a particular community, does it?
MR. CHANDLER: Objection. Scope.
MR. MASTERS: Objection.
THE WITNESS: It does not.
BY MR. ELSNER:
Q. Okay. And the quota system, even if you reduce the quota, it couldn't prevent a distributor like McKesson from distributing 112,000 doses units of Hydrocodone products into one pharmacy in West Virginia with a population of 1500 people, could it?
MR. CHANDLER: Object to form.
MR. O'CONNOR: Objection. Scope.
MR. EPPICH: Objection.
THE WITNESS: The quota system is national so it has no control over distributor contracts.

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BY MR. ELSNER:
Q. And the DEA, through the quota system, it doesn't analyze and approve individual orders from pharmacies, to manufacturers or to wholesale distributors, does it?
A. It does not.
Q. Okay. And the quota system doesn't authorize the number of pills that could be distributed into Summit County or Cabell County in West Virginia, does it?
MR. CHANDLER: Object to form.
MR. O'CONNOR: Object to form.
THE WITNESS: It does not.
BY MR. ELSNER:
Q. And it doesn't authorize the number of pills that a distributor could send to any city or county in the United States, does it?
A. It does not. It is national. It is not county, not city, not state-specific.
Q. Okay. So the DEA is really just approving a gross bulk amount of a controlled substance that a manufacturer can acquire to produce certain drugs that could be then made into any type of drug at any dose and sold into

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any town into America; is that right?
MS. McCLURE: Object to form.
MR. EPPICH: Objection. Vague.
MR. O'CONNOR: Object to form.
MR. CHANDLER: Object to form.
THE WITNESS: Quota is granted for any FDA-approved product to be distributed into the patient population.
BY MR. ELSNER:
Q. Without respect to the particular location of national scope, correct?
A. It is national in scope.
Q. Now, correct me if I am wrong, but it's the manufacturer that requests authorization to purchase a bulk amount of a certain drug; is that right?
MR. O'CONNOR: Object to form.
THE WITNESS: Correct.
BY MR. ELSNER:
Q. Okay. And at any time a manufacturer could say, I no longer want authorization to purchase these controlled substances, right?
MR. O'CONNOR: Object to form.
THE WITNESS: Correct.

BY MR. ELSNER:
Q. It's not the U.S. -- the U.S. Government cannot make a manufacturer seek an authorization to purchase bulk controlled drugs, right?
A. Correct.
Q. In fact, DEA, through the quota system, cannot make a manufacturer seek a specific authorization for a specific type of drug either, can it?
A. I don't understand the question.
Q. The DEA -- can the DEA instruct a manufacturer to seek an authorization for a specific type of controlled substance to make a particular product?
A. No, it cannot.
Q. And the DEA cannot require manufacturers or distributors to distribute controlled substance down through the supply chain, can it?
MR. MASTERS: Objection. Scope.
MR. EPPICH: Objection. Foundation.
THE WITNESS: No.
BY MR. ELSNER:
Q. Just because a manufacturer may be

able to obtain an authorization for an opioid, that doesn't mean a manufacturer needs to actually purchase the opioids, right?
MR. MASTERS: Objection. Scope.
MR. EPPICH: Objection. Foundation.
MR. CHANDLER: Objection.
THE WITNESS: Correct.
BY MR. ELSNER:
Q. And once a quota is issued, it can be increased or decreased throughout the year; is that true?
A. At the request of the manufacturer itself.
Q. Can the DEA request the manufacturer to decrease or increase the quota?
A. No.
Q. And if a manufacturer receives an authorization for a quota and purchases the bulk amount of that drug, that doesn't mean they need to use all of that drug in a given year to manufacture pills. They could spread it over several years if they informed the DEA; is that true?
MS. McCLURE: Object to form. Compound. Vague.

MR. CHANDLER: Object to form.
MR. EPPICH: Object to form.
THE WITNESS: Based on the application that the manufacturer submitted, it could -- they did not -- they do not need to use it for that year, but they should use it in the second year as an inventory allowance.
BY MR. ELSNER:
Q. The statute says that the DEA was to establish the total annual needs of controlled substances in the United States to provide for the estimated medical, scientific research and industrial needs in the U.S.; is that right?
A. And inventory allowance and export included.
Q. And one of the factors that the DEA must consider when establishing the quota is whether there is an adequate supply of a given drug; is that right?
A. Correct.
Q. And, in fact, the DEA must ensure that there is both an adequate and an uninterrupted supply of those controlled substances available for legitimate medical use and other things, correct?

A. Correct.
Q. It is also true, isn't it, that under the Food & Drug Administration Safety Innovation Act, that the FDA could request that the DEA increase quotas applicable to a particular substance if the FDA determines that's necessary; is that true?
MR. EPPICH: Objection. Vague.
THE WITNESS: Can I have that asked again, please.
BY MR. ELSNER:
Q. If the FDA is notified of a supply disruption of certain drugs that contain controlled substances subject to a quota, the FDA, under the Food & Drug Administration Safety Innovation Act, requires that the FDA request DEA to increase the quota applicable to that controlled substance if the FDA determines it's necessary; is that true?
MR. EPPICH: Objection.
MR. O'CONNOR: Objection.
MR. CHANDLER: Objection.
THE WITNESS: It requires that the FDA and DEA enter into a dialogue in order to determine whether it's necessary or not to

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increase the quota.
MR. ELSNER: I will mark this as Exhibit 10.
(Deposition Exhibit 10 was marked for identification.)
BY MR. ELSNER:
Q. This is a DEA PowerPoint presentation and it's from a presentation done in New Orleans, and it's the 11th Pharmaceutical Industry Conference.
There is not a year on the beginning of the document but we have been able to determine that that conference occurred in 2003. Okay?
A. Okay.
Q. I'm going to ask you to turn to Page 10 of the presentation. There is a slide there that reads: "Quota factors."
The second bullet there, it reads: "There is no real means of determining legitimate medical need for product substance class."
And then it says underneath that: "Because we are treating symptoms, pain, insomnia and the like."

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Do you agree with that bullet point from the DEA presentation that there is no real means of determining legitimate medical need for a product?
MR. O'CONNOR: Objection.
THE WITNESS: That is the FDA's role in all of this so DEA cannot respond to that.
BY MR. ELSNER:
Q. But just in terms of practical sense, the role of the DEA is to establish an estimate of medical need. You could never determine the exact precise medical need at any given point in time; is that fair?
MR. CHANDLER: Objection. Form.
MS. McCLURE: Objection. Form. Vague.
THE WITNESS: Correct.
BY MR. ELSNER:
Q. So you rely on a bunch of different factors to consider that, but at the end of the day, it's an estimate because you can never be exactly precise; is that true?
MS. McCLURE: Objection.
MR. O'CONNOR: Objection.
MR. CHANDLER: Object to form.

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THE WITNESS: Correct.
BY MR. ELSNER:
Q. And the third bullet there says there's no federal regulation of the practice of medicine and so the DEA cannot regulate the practice of medicine; is that true?
MR. CHANDLER: Objection. Scope.
THE WITNESS: I'm not sure of your question.
BY MR. ELSNER:
Q. Well, my question was just whether you agreed with that bullet, that the DEA cannot regulate the practice of medicine, certainly not through the quota system, correct?
MR. CHANDLER: Objection. Scope. Vague.
MR. MASTERS: Counsel, is there a Bates number for this document?
MR. ELSNER: It's on the last page.
MS. McCLURE: For purposes of the record, it is Bates 03000179742, TPLCP 030000179742.
THE WITNESS: So DEA will regulate only as far as a doctor who writes a

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prescription for a controlled substance needs to be registered with the DEA.
BY MR. ELSNER:
Q. Okay. Because there is no precise means of determining the exact medical need, one of the factors that the DEA considers are data that is provided by the manufacturers such as sales data, correct?
MR. O'CONNOR: Objection. Form.
THE WITNESS: Correct.
MS. NEWMARK: Counsel, I'm going to object to the use of this document, the Purdue document that was produced pursuant to the protective order in this case. If you would -- you haven't established a foundation for what this document -- where it came from.
MR. ELSNER: Well, it's a DEA document.
MS. NEWMARK: Did you seek permission to use it from Purdue?
MR. ELSNER: I don't need to seek permission to use a DEA document from Purdue.
MS. NEWMARK: Well, you haven't -- it is marked confidential. You have not established that this is a DEA document.

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BY MR. ELSNER:
Q. Ma'am, is there a DEA logo on the front page of the document?
A. Yes.
Q. Does it read DEA OD 11th Pharmaceutical Industry Conference?
A. Yes.
Q. Okay. Isn't it true that individual quotas for each registrant are calculated based on the business activities and justification they provide to the DEA?
MR. O'CONNOR: Objection. Form.
THE WITNESS: It's based on their business activities and a part of it on their justification, yeah.
BY MR. ELSNER:
Q. Okay. And you'd agree that the quality of the data -- that the quality of the quota calculation is based on the quality of the data provided in part by the manufacturers. Would you agree with that?
MR. O'CONNOR: Objection. Form.
MR. EPPICH: Objection. Vague.
THE WITNESS: Part of that data is the consideration, yes.

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BY MR. ELSNER:
Q. Okay. And there would be an expectation that the data that would be provided would be both accurate and complete, right?
MR. EPPICH: Object to form. Vague.
THE WITNESS: So DEA was -- is skeptical of data submitted by the manufacturers and therefore relies on the third-party prescription data as well.
BY MR. ELSNER:
Q. For sure. And we will get to the prescription data.
Why is the DEA skeptical of the data provided by manufacturers?
MR. O'CONNOR: Objection. Form.
THE WITNESS: Because based on the business activities, the manufacturers may not fully state what is actually being -- what is actually necessary for patient consumption.
BY MR. ELSNER:
Q. And when they do that, that could impact the size of the quota, correct?
A. Correct.
Q. When the DEA is reviewing the sales data as reported by the manufacturers, does the DEA have the ability to actually look in realtime behind the sales data that is provided?

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MR. O'CONNOR: Objection to form.
THE WITNESS: No.
BY MR. ELSNER:
Q. And so, in part, you are relying on -- although you are skeptical, you are relying on the information that the manufacturers provide to you in order to assess legitimate medical need in part, correct?
MR. CHANDLER: Objection. Form.
MR. O'CONNOR: Objection. Form.
MR. EPPICH: Objection. Form.
THE WITNESS: Yes.
MR. ELSNER: This is Exhibit 11.
(Deposition Exhibit 11 was marked for identification.)
BY MR. ELSNER:
Q. I'm going to ask you to -- it's a collection of e-mails. I'm going to ask you to turn to the very last page of the document.
This is an e-mail from Richard Sackler of Purdue.

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MS. NEWMARK: Objection to form.
BY MR. ELSNER:
Q. And he writes: "I think we should move our allocation upward again. I believe that we should be able to handle an increase up to 175 million for this year in demand and well above 200 million next year. Michael will give you numbers today but I think this is close to ballpark."
Then he asks: "What is our allocation for now? Am I right in estimating that we are earning about $60,000 per kilogram sold. If so, it would appear that we need about 2,925 kilograms of oxycodone HCL for this year and something approaching 4,000 kilograms next year."
Did I read that correctly?
A. Yes.
MR. O'CONNOR: Object to form.
MS. NEWMARK: Object to form, and I'm going to object to the use of this e-mail. Once again, this is a Purdue document that was produced pursuant to a confidentiality order. There is no indication that -- yet again, that counsel sought permission to use this e-mail

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and it's outside the scope of the permit.
BY MR. ELSNER:
Q. Did DEA know that Purdue had internal estimates that they could earn $60,000 for every kilogram of oxycodone authorized?
MR. O'CONNOR: Objection to form and scope.
MR. CHANDLER: Objection to scope and I will instruct witness not to answer. Specifically excluded from the deposition notice, any consideration of particular quota amounts for particular years for particular registrants.
MR. ELSNER: My question -- my question is not to analyze whether the DEA considered any specific quota requests from any manufacturer.
My question is simply whether the DEA was aware that certain manufacturers were calculating quota based on the dollars they could earn off the kilograms authorized. That's my question.
MR. O'CONNOR: Objection.
MR. CHANDLER: With reference to this particular e-mail and those particular

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amounts, I'm going to instruct the witness not to answer that.
BY MR. ELSNER:
Q. Was the DEA aware, ma'am, that manufacturers of opioids were establishing quota based on the dollars they could earn off the quota authorized?
MR. O'CONNOR: Objection to form.
MS. NEWMARK: Object to form. Object to foundation.
MR. CHANDLER: Object to form.
THE WITNESS: The DEA was not aware.
BY MR. ELSNER:
Q. The quota authorization was supposed to be based on legitimate medical need, correct?
A. Yes.
Q. It's not supposed to -- it's not supposed to be based on how much profit you can earn of the quota authorized, correct?
MR. O'CONNOR: Objection.
THE WITNESS: Correct.
BY MR. ELSNER:
Q. And if you calculate a quota based on how much you could earn instead of

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legitimate medical need, it could offset an impact to the quota authorization, right?
MR. O'CONNOR: Objection. Form.
MR. CHANDLER: Objection. Vague. Form.
THE WITNESS: I'm not -- I don't understand your question.
BY MR. ELSNER:
Q. Okay. If a manufacturer was seeking authorization of quota, not by determining actual medical data but instead by determining how much profit they could earn, that could offset the quota authorization, correct?
MS. McCLURE: Objection to form. Foundation. Vague. Compound.
MR. CHANDLER: Objection. Form.
MR. O'CONNOR: Objection.
MS. McCLURE: Calls for speculation.
THE WITNESS: The DEA would seek a third-party data in terms of trying to determine actual legitimate medical need for that particular manufacturer.
BY MR. ELSNER:
Q. I understand that the DEA has other systems it could use. It looks at IMS data,

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prescription data, we're going to get there.
But my question is is that if manufacturers were giving the DEA data and requesting quota authorizations based on the profit they could earn instead of legitimate medical need, that could impact the quota authorization?
MR. CHANDLER: Objection.
MS. McCLURE: Same objection.
MR. CHANDLER: Vague. Calls for speculation. Objection to form.
THE WITNESS: If a manufacturer used that process, then they would probably overestimate the amount of quota.
BY MR. ELSNER:
Q. Just above the e-mail from Richard Sackler, there is an e-mail from James Sullivan, and at the end of the second paragraph, he says: "I'd asked for 1,1800-plus and I have been given 1,412. I will ask for a plus-700 and probably get 400, then go back again in the summer for more."
MS. NEWMARK: Counsel, again, I'm objecting to the use of this e-mail. This e-mail was produced in a different litigation

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pursuant to a confidentiality order and Mr. Chandler already instructed the witness not to answer subject to that.

MR. MASTERS: And further, I would add that pursuant to the DEA's authorization letter, to the extent that these -- that this e-mail reflects procurement quota applications, it is outside the scope of the DEA authorization which is not the decision with respect to individual procurement quota for any given year.

BY MR. ELSNER:

Q. My question is whether the DEA was aware that manufacturers would sometimes ask for more quota than they actually needed with the hope that they would -- sorry, my question is whether -- let me strike that.

My question is whether DEA was aware that manufacturers would sometimes ask for more quota than they actually needed.

MR. O'CONNOR: Objection to form.

MR. CHANDLER: Objection. Scope.

MS. McCLURE: Form. Speculation. Foundation.

MR. MASTERS: We object as well.

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MR. CHANDLER: You can answer.

THE WITNESS: DEA was aware that manufacturers asked for larger quotas than was supported by actual documentation.

BY MR. ELSNER:

Q. Was that another reason the DEA was skeptical of manufacturer's quota requests?

A. Yes.

Q. Among the factors that the DEA would look at in examining a mid-year quota change, would they look at sales compared to inventory?

A. Yes.

Q. And so if a manufacturer was able to show a lot of sales and no inventory, then that might support an increase in their quota authorization; is that right?

MR. CHANDLER: Objection. Calls for speculation. Incomplete hypothetical.

MR. O'CONNOR: Objection.

MS. McCLURE: Object to form. Scope.

MR. MASTERS: Objection to highlighting part of the document rather than the entire paragraph.

MS. McCLURE: Objection as to the instruction as to whether this witness is permitted to answer questions regarding individual situations or not.

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MR. CHANDLER: You can answer the question subject to my objection.

THE WITNESS: If a manufacturer suggested that their sales outpaced and that they had used up their inventory, it would result in probably a higher quota.

MR. ELSNER: Mark this document as Exhibit 12.

(Deposition Exhibit 12 was marked for identification.)

MS. McCLURE: For the record, could you please read the confidentiality designation that may appear on the document as well as the Bates numbers for the record as per the deposition protocol.

MR. ELSNER: I will give the Bates numbers. P 2421610 through 1612.

MS. NEWMARK: Object to the extent this is in violation of the protective order in this case and the information that appears in the foot of the document is in a different lawsuit.

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And I am going to repeat the same objection and object again to the fact that this is a highly confidential document and as counsel -- Mr. Chandler stated before, he instructed his client not to answer and this is outside the scope of the designations for which the witness was designated to testify.

BY MR. ELSNER:

Q. I'm going to ask you to look at the last page of the document here.

The third to last paragraph just under "total available," it reads: "Based on the conversation with DEA recently, their stated position is that Rhodes will not be awarded additional quota allocation until we generate sales and submit a new quota request. My recommendation is to ship (sell) every kilogram we can from Rhodes in April, hold back only what we estimate R&D may want for development purposes. Rhodes would then prepare and submit a new quota request to DEA on May 1st for 3,000-plus kilograms and a 50 percent inventory build allowance or a total of 4,500-plus kilograms."

Did I read that correctly?

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MS. NEWMARK: Objection.
MR. O'CONNOR: Objection.
MS. NEWMARK: Again to the use of this document.
MR. ELSNER: Your objection is preserved. You don't need to give a speaking objection that lasts three minutes every time.
MS. NEWMARK: I'm going to keep repeating my objection as long as you keep trying to violate the confidentiality order in this case and in the Kentucky case.
MS. McCLURE: I will note for the record the inconsistent instruction from DEA counsel as to whether witnesses are or are not permitted to answer questions.
MR. MASTERS: Objection.
MR. CHANDLER: And I am going to object on scope grounds, and instruct the witness not to answer.
Again, the witness is not designated to testify about individual determinations as to particular registrants, particular years, particular substances and I -- if you want to ask about a policy or a practice, that's fine, but I don't see any connection between this

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document and the policy or practice.
MR. ELSNER: I appreciate the objection. I just haven't asked the question yet.
BY MR. ELSNER:
Q. My question is, is that if a manufacturer was selling all the product that they have and then requesting a mid-year review saying that we sold all of our product and our inventory is down to nothing, would that potentially impact the DEA's decision to increase their quota?
MR. CHANDLER: And --
MR. O'CONNOR: Objection.
MR. CHANDLER: -- I'm going to object on scope grounds, and if you are asking the question in the abstract separate from Exhibit 12, then I will allow the witness to answer.
Subject to the further objection that it is vague, calls for speculation and it's an incomplete hypothetical.
MS. McCLURE: Objection. Incomplete hypothetical. Objection to form, speculation and scope.

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MR. CHANDLER: You can answer without reference to the document.
THE WITNESS: If a manufacturer came for a mid-year revision for a quota because it sold all that it had, DEA would consider that, but once again, with a skeptical eye and a look to third-party data to see that prescriptions were being filled.
BY MR. ELSNER:
Q. But it could potentially impact the quota authorization, correct?
MS. McCLURE: Same objection.
MR. CHANDLER: Same objection.
MR. O'CONNOR: Objection.
THE WITNESS: It could.
MR. ELSNER: Why don't we take a quick break.
THE VIDEOGRAPHER: We are going off the record. This is the end of Media Unit No. 4. The time is 3:23.
(A short recess was taken.)
THE VIDEOGRAPHER: We are going back on the record. This is the start of Media Unit No. 5. The time is 3:44.
You may proceed, Counsel.

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MR. ELSNER: Thank you.
BY MR. ELSNER:
Q. Ma'am, as you pointed out, the DEA didn't just rely on the manufacturer's information to set quota. The DEA also looked at prescription data; is that true?
A. Correct.
MR. O'CONNOR: Object to form.
BY MR. ELSNER:
Q. And did that include data provided by IMS and later equivalence of that company?
A. Yes.
Q. And would you agree with me that if manufacturers and distributors of opioids had misled doctors and the public about the health benefits and the addictive nature of opioids they were manufacturing and distributing causing sales to rise, then the DEA's estimate of the medical need could be above the actual medical need in the United States?
MR. CHANDLER: Objection.
MS. McCLURE: Objection. Form. Speculation. Incomplete hypothetical. Vague. Compound. Foundation.
THE WITNESS: Yes.

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BY MR. ELSNER:
Q. And among the factors that could impact quota and the medical need, if you turn to -- back to Exhibit 10, which is a PowerPoint and I will ask you to look at Page 28. This is the DEA's PowerPoint again.
And the heading on the top of the PowerPoint says: "Factors hindering determination of legitimate medical need."
Did I read that correctly?
A. Yes.
Q. Okay. And one of those factors on the bottom is an unusually aggressive, innovative, persuasive marketing and promotion. Would you agree that that would potentially impact the determination of legitimate medical need?
MR. CHANDLER: Object to form.
MR. O'CONNOR: Object to form.
MS. McCLURE: Same objection. Speculation.
THE WITNESS: It would definitely overestimate legitimate medical need.
BY MR. ELSNER:
Q. Okay. Now, the DEA doesn't have

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control over the marketing and promotional activities of manufacturers; is that correct?
MR. O'CONNOR: Object to form.
MR. CHANDLER: Objection. Scope.
MS. McCLURE: Foundation.
THE WITNESS: Correct.
BY MR. ELSNER:
Q. Now, this slide has some pictures in it. It has a stuffed animal and it has a mug, it reads: "The one to start with." And then the other mug has "OxyContin" written on it.
Do you see that?
MR. EPPICH: Objection. Foundation. Speculation.
THE WITNESS: Yes.
BY MR. ELSNER:
Q. Are these some promotional items that Purdue would send out?
MS. McCLURE: Foundation.
MS. NEWMARK: Objection. Foundation. Form.
MR. EPPICH: Scope.
MR. CHANDLER: Objection. Form.
THE WITNESS: I'm unaware of the promotional items that they sent out.

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BY MR. ELSNER:
Q. Okay. If you look at the notes at the bottom of the slide under the heading: "Unusually aggressive, innovative, persuasive marketing promotion."
Do you see where I am at?
A. Yes.
Q. The first bullet reads: "Much more promotional money spent on OxyC than equivalent products."
Could that promotional money spent on OxyContin impact the determination of legitimate medical need of the DEA?
MR. CHANDLER: Objection. Vague.
MR. EPPICH: Objection. Foundation. Form. Outside the scope.
MR. CHANDLER: Objection. Foundation. Form.
THE WITNESS: Only if it impacted physician's prescription writing.
BY MR. ELSNER:
Q. And there are a number of other bullets here.
The second one reads: "Scope of the medical specialty groups promoted to the widest

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for OxyC."
Next is: "IMS messaging site. Physicians heard use OxyC for moderate to severe pain, acute and chronic pain."
Next one: "Effective pain relief, use it for everyone."
Next one: "OxyC reports of diversion and abuse routinely downplayed."
These are all items listed as factors that could hinder the determination of legitimate medical need in the DEA's presentation; is that true?
MR. O'CONNOR: Objection. Form. Scope.
MR. CHANDLER: Objection. Form.
THE WITNESS: Correct.
BY MR. ELSNER:
Q. Do you agree with them?
MR. CHANDLER: Objection. Scope. Form.
THE WITNESS: If those statements are true, they would impact estimations of legitimate medical need.
BY MR. ELSNER:
Q. Okay. And if these extensive

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marketing campaigns encouraged doctors to prescribe and patients to seek opioids for the treatment of ankle sprains and backaches and all other types of nonchronic pain, and sales increased dramatically, it would impact the DEA's estimate of potential medical need because it would impact the number of prescription written, correct?

MR. CHANDLER: Objection. Vague. Incomplete hypothetical. Form.

MR. MASTERS: Form. Foundation. Speculation.

MS. NEWMARK: Scope.

MR. O'CONNOR: Objection. Form.

THE WITNESS: DEA does not determine which legitimate medical needs require controlled substances and which ones do not. That is up to the FDA and the physicians themselves.

BY MR. ELSNER:

Q. If you turn to Page 29 in the presentation.

The top of the slide reads: "The limitations of quotas."

Did I read that right?

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A. Yes.

Q. Okay. And it shows dollars in thousands and it shows OxyContin reaching over $1.6 billion in total sales.

Do you see that in the red bar?

A. Yes.

Q. And then on the bottom, there's some notes from DEA and there is a heading that says: "Drawbacks of quotas."

Do you see that?

A. Yes.

Q. Then there is: "Marketing promotional techniques," that's underlined.

Do you see that?

A. Yes.

Q. And it reads: "Massive promotional dollars spent."

Did I read that correctly?

A. Yes.

Q. "Promoted to nontraditional pain specialty groups implied and inferred OxyContin messages to prescribers."

Did I read that correctly?

A. Yes.

Q. Okay. This presentation lists these

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as factors that could limit -- under the limitations of quotas, do you agree that marketing these products to nontraditional pain groups and spending massive promotional dollars could impact the quota and the definition of legitimate medical need?

MR. O'CONNOR: Objection. Form.

MR. CHANDLER: Objection. Form. Scope. Foundation. Form.

THE WITNESS: They would limit quota, yes.

BY MR. ELSNER:

Q. Okay. If -- you said, "they would limit quota."

Do you mean -- I just want to make sure I understand. Are you saying that these types of activities, they would limit the ability to accurately determine quota; is that what you mean?

A. Correct.

MR. CHANDLER: Objection. Scope. Foundation. Form.

MR. O'CONNOR: Object to form.

BY MR. ELSNER:

Q. If you could turn to Page 11 of the

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presentation.

The title of this slide is: "Consumption of analgesics for the treatment of moderate to severe pain."

Is that what it says?

A. Yes.

Q. And it shows that the number of prescriptions for the -- the number of prescriptions for the treatment of moderate to severe pain increased as a result of the those promotional activities from '98, '99 through 2002, correct?

MR. CHANDLER: Objection. Scope. Foundation.

MR. EPPICH: Objection. Foundation. Form.

THE WITNESS: So it shows that prescriptions increased.

BY MR. ELSNER:

Q. For the treatment of moderate to severe pain, correct?

A. Correct.

Q. And consequently, the quota authorization also increased, correct? In the red bars?

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MR. CHANDLER: Objection. Form. Foundation.
THE WITNESS: Yes.
BY MR. ELSNER:
Q. Okay. Now if the supply was limited -- so I am done with the document now.
If the supply were limited, if you decreased the quota, would that stop all diversion?
MR. CHANDLER: Objection. Form.
THE WITNESS: No.
BY MR. ELSNER:
Q. It would simply mean that the gross bulk amount of a particular gross drug type would be less, right?
MR. CHANDLER: Objection. Form.
THE WITNESS: Can you repeat the question.
BY MR. ELSNER:
Q. It would simply mean that gross bulk amount of a particular gross drug type would be less, correct?
MR. CHANDLER: Same objection.
MR. O'CONNOR: Object to form.
THE WITNESS: Correct.

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BY MR. ELSNER:
Q. Okay. And when it was reduced, it would be reduced both for the illicit market and the licit market, correct?
MR. MASTERS: Objection. Scope.
MS. McCLURE: Objection. Form. Speculation. Foundation.
MR. CHANDLER: Objection. Form.
THE WITNESS: The quota is only for the legitimate medical needs and so it's only for the legitimate market.
BY MR. ELSNER:
Q. But we recognize that pills are diverted, correct?
MR. O'CONNOR: Objection. Form.
MS. McCLURE: Foundation.
MR. CHANDLER: Objection.
THE WITNESS: Yes.
BY MR. ELSNER:
Q. And so if we reduce the size of the quota simply reduces the pool of available drugs, both to the licit and illicit users of that drug, correct?
MS. McCLURE: Form. Foundation. Speculation. Scope.

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MR. CHANDLER: Object to form.
MR. O'CONNOR: Object to form.
THE WITNESS: It reduces the amount of material available, period.
BY MR. ELSNER:
Q. Across the board?
A. Across the board.
MR. EPPICH: Object to form.
MS. McCLURE: All the same objections.
BY MR. ELSNER:
Q. In 2001, the DEA administrator Donny Marshall testified before Congress.
Are you familiar with that testimony?
A. I am.
Q. Okay.
MR. ELSNER: I'm going to mark it as the next exhibit.
(Deposition Exhibit 13 was marked for identification.)
BY MR. ELSNER:
Q. I'm going to ask you to turn to Page 115 of 228.
MS. McCLURE: Can you read the Bates

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number into the record.
MR. ELSNER: There is not a Bates number but this is the -- it's testimony of Donny Marshall before a subcommittee of the committee of appropriations in the House of Representatives in 2001.
BY MR. ELSNER:
Q. And about in the middle of the page, there is a paragraph that -- it begins with: "We begin to see this problem."
Do you see where I am at?
A. Yes.
Q. Okay. And he is asked about oxycodone and he says: "We begin to see this problem as a result of some developments that began four or five years ago. What we saw about four or five years in 1996 or thereabouts, was that the AMA and a number of pain management groups that made the case and contended that we are under-treating pain in this country or that we are not effectively treating pain in this country."
Did I read that correctly?
A. Yes.
Q. And if you go to the next page, in

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the middle of the paragraph, it starts at the third full paragraph: "We are asking the industry to do several things."

Do you see where I am at?

A. Yes.

Q. It says: "No. 1, we are asking that the company do a more balanced approach in their marketing of this drug. We are asking them to educate doctors and patients about the dangers of the drug. We are asking them not to advertise in such a way that gives a physician, for instance, who is not well-trained in pain management, it gives that physician the impression that this might be the painkiller of first resort rather than the painkiller of last resort. We are asking them and others perhaps to come up with what we refer to as a restricted distribution, in other words, recommend that doctors only prescribe and pharmacists only distribute this for certain types of pain, so that the kidney stone patient may get a different version of it, but the terminal cancer patient may well get the 160 milligram oxycodone."

Do you see that?

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A. Yes.

Q. Did I read it correctly?

A. Yes.

Q. Okay. And then in the second to last paragraph, he states: "Frankly, the manufacturer of this, they have met us on some of these issues, on others, they have not met us."

And then he says: "And I have to tell you, sir, that we need more cooperation from that company, and if we cannot find some more middle ground in this area, I am seriously considering rolling back the corners of th quotas that the DEA set, rolling back those quotas to 1996 levels until we find ways to control this."

Did I read this correctly?

A. Yes.

Q. Were you aware that the DEA was considering rolling back quotas to 1996 levels for oxycodone?

MR. CHANDLER: Objection. Scope.

MR. O'CONNOR: Objection.

THE WITNESS: I am aware that it had been considered.

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MR. ELSNER: Mark this next document as the next exhibit.

(Deposition Exhibit 14 was marked for identification.)

MR. ELSNER: It bears the Bates range PPLPC045 and then a bunch of zeros, 5405 through 5425.

BY MR. ELSNER:

Q. Was the DEA aware --

MS. NEWMARK: I will object to the use of this document. I have not gotten a chance to look through it but it appears to be a Purdue produced e-mail and you are showing it to the witness in violation of the protective order as it's marked confidential, and you did not seek permission from Purdue to show this to the witness.

MR. ELSNER: First, your understanding of the protective order is wrong. Section 33M states that there is only a restriction in sharing it with another -- an employee of another party. This is not another party in the litigation. So your objection is completely wrong.

Furthermore, the Government has

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signed the confidentiality order and they're -- and I am entitled to use it in this deposition and I don't need to ask for permission.

Secondly, the repeated extensive objections are interfering with the flow of the deposition unnecessarily, and I think intentionally, and I ask you simply to say objection. Your objections are always preserved and you can raise them at a later time.

MS. NEWMARK: Counsel, I am entitled to object to whenever you ask a question that is objectionable. Furthermore, under Section 33H of the confidentiality order, if a designee -- you're required to give the designee party notice of your intent to disclose a document to state or federal law enforcement agencies, even if they have completed the certification in Exhibit A and the acknowledgement to be bound, and if the designating party, which here is Purdue, objects to the disclosure, then the designating party may request a meet and confer and resolve the protective order from the Court.

MR. ELSNER: This is not that

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situation. I'm not disclosing it for that situation.
MS. NEWMARK: This is that situation, and we can call Colin right now if you want to have a dispute about this.
MR. ELSNER: Well, we have a dispute about it, but we are not going to waste any more time. Your objection is preserved.
MS. NEWMARK: I'm going to continue to object to your use of this document and furthermore, it is outside the scope of what this witness is permitted to testify about today.
BY MR. ELSNER:
Q. Ma'am, were you aware that Purdue, in response to Mr. Marshall's testimony, began writing letters to its customers, to pain management groups and to members of Congress?
MR. O'CONNOR: Objection. Form. Scope.
MR. CHANDLER: Objection. Scope.
MS. NEWMARK: Objection. Foundation.
THE WITNESS: The DEA is aware of that.

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BY MR. ELSNER:
Q. Okay. I'm going to ask you to look at the second page of the document. This is one of the drafts.
MS. NEWMARK: So again, I'm going to object to the use of this document.
MR. ELSNER: Your objection is preserved.
MS. NEWMARK: That it's violating the protective order in this case, and I'm going to keep objecting as long as you keep violating the protective order.
MR. ELSNER: I'm going to ask questions on this document. Your objection is preserved. You don't need to raise it every single question that I ask. It's preserved. You can simply say objection.
BY MR. ELSNER:
Q. I'm going to ask you to look at the middle of this document, at the end of the second full paragraph.
It reads: "The 1996 level would represent a 95 percent reduction in raw material allowing only one prescription of 20 to be filled."

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Did I read that correctly?
A. Yes.
Q. Okay. It reads that -- under that: "In human terms, such a rollback would mean, No. 1, in 1996, the amount of oxycodone allocated to Purdue allowed us to supply enough OxyContin to fill approximately 29,000 prescriptions per year. In 2000, the amount of oxycodone allocated to Purdue allowed us to supply enough OxyContin to fill approximately 5.4 million prescriptions a year."
It then says, under Item 3: "If the quota were reduced as suggested by Mr. Marshall, we would not be able to supply 95 percent of the demand for OxyContin. 19 out of every 20 patients would be unable to fill their doctor's prescriptions."
Did I read that correctly?
A. Yes.
Q. On the next page, the second paragraph, the first line reads: "If the DEA were to impose even a small restriction on Purdue's quota for oxycodone, the war on drugs would turn into a war on people in pain."
Did I read that correctly?

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A. Yes.
Q. Was the DEA aware that Purdue was sending letters out to its customers telling them that the DEA was engaged in a war on people in pain?
MR. O'CONNOR: Objection. Form. Scope.
MR. CHANDLER: Objection.
MS. NEWMARK: Objection. Foundation.
MR. O'CONNOR: Can the DOJ instruct the witness not to answer on the basis of scope.
MR. CHANDLER: No. The witness can answer.
THE WITNESS: I'm not sure we -- DEA was aware of it going to actual patients. We knew it went to Congress.
BY MR. ELSNER:
Q. And the DEA wasn't engaged in a war on people in pain, was it?
MR. O'CONNOR: Objection. Scope.
MR. CHANDLER: Objection. Foundation.
THE WITNESS: No.

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BY MR. ELSNER:
Q. You were trying to set the legitimate medical need for the country, correct?
A. Correct.
MR. EPPICH: Objection. Vague.
BY MR. ELSNER:
Q. Among the items that the DEA was attempting to work with manufacturers on, which included a more balanced approach to marketing, better education, better -- less advertising, those items including the addictive nature of the drug are not revealed in this letter, are they?
MR. O'CONNOR: Objection. Form. Scope.
MR. CHANDLER: Objection. Form.
THE WITNESS: No, it does not look like it.
BY MR. ELSNER:
Q. If you turn to the next letter, the next draft letter, you mentioned that you were aware that letters had been sent from Purdue to members of Congress.
This is a draft letter to be sent to

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Congressional members in North Carolina, and in this letter, Purdue is threatening that they are going to close their plant in Wilson, North Carolina, if the 1996 rollback occurs.
Was the DEA aware of that?
MR. O'CONNOR: Objection. Form. Scope. Mischaracterizes prior testimony.
THE WITNESS: DEA knew that manufacturers tended to threaten Congress with closing their facilities.
BY MR. ELSNER:
Q. Okay. If we turn to --
MR. ELSNER: Mark this as the next exhibit.
(Deposition Exhibit 15 was marked for identification.)
MR. ELSNER: This is another Purdue document. Your objections are preserved.
MS. NEWMARK: I'm going to repeat my objection. Obviously an objection to the use of the prior document, the document is under the protective order in this case and counsel's violating Section 33H of the protective order by continuing to use all of these Purdue documents that are clearly marked confidential.

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BY MR. ELSNER:
Q. If you look at the bottom of the first page of this exhibit, there is a dash 8 there.
And it reads: "A version of this letter should go to pain physicians as well. This is a clear attack on the pain movement. There can be no other interpretation."
Did I read that correctly?
A. Yes.
Q. And was the DEA trying to attack the pain movement by trying to set the appropriate quota authorization for oxycodone?
MR. O'CONNOR: Objection.
MR. EPPICH: Objection. Scope.
THE WITNESS: No.
BY MR. ELSNER:
Q. The DEA was just simply trying to correctly determine the legitimate medical need for oxycodone; is that right?
MR. O'CONNOR: Objection.
MR. EPPICH: Objection. Calls for speculation.
MR. CHANDLER: Objection. Form.
THE WITNESS: So the DEA was hoping

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to find that the FDA would provide better data for legitimate medical need, yes, as they are the agency required to do so.
BY MR. ELSNER:
Q. But the DEA was not trying to attack the pain movement in trying to set the right quota, correct?
MR. O'CONNOR: Objection. Form.
THE WITNESS: Correct.
BY MR. ELSNER:
Q. Now, under No. 10, it says: "The AAFP," this is the American Association of Family Practitioners, "would be very interested in this testimony. Want me to call Henely or to send him an e-mail this weekend with the testimony? He will be incensed at the suggestion that prescribing will be limited."
Did I read that correctly?
A. Yes.
Q. Now one of the things that the DEA was hoping to work cooperatively with the industry with, was to restrict the number of doctors who could prescribe this medication to those who specialized in pain management, correct?

MR. O'CONNOR: Object to form. Scope.
MR. CHANDLER: Objection to scope. I will instruct the witness not to answer that one.
BY MR. ELSNER:
Q. Was the DEA aware that Purdue was sending letters to pain physicians and to pain -- patient advocacy groups to oppose Mr. Marshall's testimony in the quota authorization?
MR. O'CONNOR: Objection. Form. Scope.
THE WITNESS: I'm unaware that the DEA knew about that.
BY MR. ELSNER:
Q. Okay. If you turn to the second to the last page of the document, the document bearing the Bates number -- the last numbers being 5403.
There is a comment there on the right-hand side and it reads: "Again, if this becomes public, do we think that our employees will understand that we don't expect the reduction in quota to happen, wouldn't it be

better to make this point verbally over the telephone rather than in a letter, which may be leaked intentionally or unintentionally. I'm sure that between us three, we can get eventually every Senator and Congressman we want to talk to us on the phone in the next 72 hours."
Did I read that correctly?
A. Yes.
Q. Was the DEA aware that Purdue had done an outreach by phone to members of Congress?
MR. O'CONNOR: Object to form.
MR. CHANDLER: Objection to form. Foundation.
THE WITNESS: DEA was aware that there was an outreach to Congress, not the form that it took.
BY MR. ELSNER:
Q. If you turn to --
MR. ELSNER: Actually, can we go off the record real quick.
THE VIDEOGRAPHER: We are going off the record. The time is 4:15.
(A short recess was taken.)

THE VIDEOGRAPHER: We are back on the record. The time is 4:34.
You may proceed, Counsel.
(Deposition Exhibit 16 was marked for identification.)
BY MR. ELSNER:
Q. I placed before you Exhibit 16 which is the letter that was written by the American Academy of Pain Management to the DEA, Donnie Marshall, on June 8, 2001.
Do you see that?
A. Yes.
Q. And this is in response to Mr. Marshall's testimony, and if you go to the middle of the second paragraph, it begins: "CSA requirement."
Do you see where I am at? "For determination of legitimate medical need."
You can see it on the screen perhaps?
A. Yes.
Q. Okay. It reads: "CSA requirement for determination of legitimate medical need is based on the undisputed position that patients and pharmacies should be able to obtain

sufficient quantities of any Schedule II drug to fill prescriptions. A therapeutic drug should be available to patients when they need it."
Did I read that correctly?
A. Yes.
Q. Okay. And then on the next page in the second full paragraph, second sentence, it states -- in the second sentence: "For 30 years, the U.S. Government has waged a war against this epidemic problem with limited success, choking off the supply of one opioid analgesic oxycodone does not solve the underlying problem of consumer demand. In fact, declaring oxycodone highly dangerous only adds to its mystique and desirability by drug abusers and addicts."
Did I read that correctly?
A. Yes.
Q. In the next paragraph, it says that: "The manufacturer of the most highly sought after form of oxycodone, Purdue Pharma L.P., is one of the most ethical pharmaceutical companies in the United States."
Did I read that correctly?

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A. Yes.
Q. When the DEA received this letter, did it know that Purdue Pharma had provided financial support for this organization?
MS. McCLURE: Objection. Foundation. Form.
MR. O'CONNOR: Objection.
THE WITNESS: I do not think DEA was aware of that.
BY MR. ELSNER:
Q. The next sentence in that paragraph, it says: "Unlike many other pharmaceutical companies, Purdue Pharma consistently offers the best continuing medical education conferences, does not engage in covert bribery and even discourages its representatives from providing alcohol."
This was at least five years before Purdue pled guilty in federal court; is that correct?
MR. O'CONNOR: Objection.
MR. CHANDLER: Objection. Scope.
MS. McCLURE: Objection. Form.
MS. NEWMARK: Objection. Form.
MR. EPPICH: Foundation.

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THE WITNESS: I don't remember the exact year that they were in court.
BY MR. ELSNER:
Q. You do remember that Purdue has pled guilty to a felony of misbranding their drug with an intent to defraud and mislead?
MR. CHANDLER: Objection. Scope.
MS. NEWMARK: Objection.
MR. O'CONNOR: Objection.
BY MR. ELSNER:
Q. Are you aware of that?
A. Yes.
Q. This wasn't the only letter that DEA received in response to Mr. Marshall's testimony, was it?
MR. O'CONNOR: Objection. Form.
MR. CHANDLER: Objection. Foundation. Form.
THE WITNESS: Not that I'm aware of.
BY MR. ELSNER:
Q. And the letter doesn't indicate, does it, that Purdue had given financial support to this organization, the American Academy of Pain Management, does it?
MR. O'CONNOR: Objection. Form.

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Foundation. Scope.
MR. CHANDLER: Objection. Form.
Unless you want the witness to spend the next few minutes reading through the entire letter.
You can answer.
THE WITNESS: I haven't read the full letter but -- so I don't know.
BY MR. ELSNER:
Q. I will represent to you that it doesn't, but in April of 2018 --
MR. ELSNER: Can I see -- we will mark this as the next exhibit.
(Deposition Exhibit 17 was marked for identification.)
BY MR. ELSNER:
Q. In April of 2018, the DEA published a notice of proposed rulemaking related to quotas, and if you look on the summary, it reads: "The Drug Enforcement Administration is publishing this proposed rule to strengthen controls over diversion of controlled substances and make other improvements to the quota management regulatory system for their production, manufacturing and procurement of

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controlled substances."
Did I read that correctly?
A. Yes.
Q. And the purpose in the third column on the first page in the second full paragraph, where it starts: "The current regulations."
Do you see where I am at?
A. Yes.
Q. "The current regulations issued initially in 1971 need to be updated to reflect changes in the manufacture of controlled substances, changing patterns of substance abuse and markets in illicit drugs, and the challenges presented by the current national crisis of controlled substance abuse. This proposed rule modifies the regulations to strengthening controls over diversion."
Was that the intent?
MR. O'CONNOR: Objection.
THE WITNESS: Yes.
BY MR. ELSNER:
Q. And if you go to the next page in the regulations, in the second full paragraph beginning with "first."
Do you see where I am at?

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A. Yes.
Q. It reads: "First, it would" --
MR. CHANDLER: I'm going to object to the characterization of this document as the regulations.
MR. ELSNER: I didn't mean to suggest. I meant the proposed regulation.
MR. CHANDLER: I just wanted to be clear.
MR. ELSNER: No problem.
BY MR ELSNER:
Q. The proposed regulation as expressed here in that paragraph reads: "First, it would add to the list the extent of any diversion of the controlled substance in the class."
Did I read that correctly?
A. Yes.
Q. Okay. Is this the first time that diversion is expressly mentioned in the statute or in the regulatory scheme related to quotas?
MR. EPPICH: Object to form. Foundation. Vague.
THE WITNESS: Yes.
BY MR. ELSNER:
Q. Okay. And so prior to this, there

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was no expressed list or item in any of the regulations related to quota that mentioned diversion; is that right?
MR. O'CONNOR: Objection.
THE WITNESS: Correct.
BY MR. ELSNER:
Q. Okay. In the end of the -- say, the -- the proposed regulation also expressly permits the DEA to consider state's relevant data from its prescription monitoring program; is that true?
MR. CHANDLER: Objection. Vague.
THE WITNESS: To allow DEA to consider data from the states, yes.
BY MR. ELSNER:
Q. And the other thing that it expressly clarified at the bottom of the second column on this page, the last full paragraph.
Do you see where I'm at?
A. Yes.
Q. Okay. It reads: "The proposed rule would amend Section 1303.12(b) to clarify that the administrator may require additional comparable information from applicants that may help to detect or prevent diversion including

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customer identities and the amounts of controlled substances sold to each customer."
Did I read that correctly?
A. Yes.
Q. Is this the first time where the DEA has -- where there is a proposed rule for the DEA to expressly consider customer information from manufacturers?
MR. O'CONNOR: Objection. Foundation.
MR. EPPICH: Objection. Foundation. Scope.
THE WITNESS: I don't understand the question.
BY MR. ELSNER:
Q. Okay. The proposed rule provides that manufacturers could -- clarifies that the manufacturers may be required to provide information about their customers; is that right?
A. Correct.
Q. Why was that important?
MR. CHANDLER: Object to form.
MR. O'CONNOR: Objection.
MR. CHANDLER: Scope.

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THE WITNESS: One factor that arose with this proposed rule was to remind manufacturers of their requirements to know their customers.
BY MR. ELSNER:
Q. And why were you reminding manufacturers of that responsibility?
MR. O'CONNOR: Objection. Form. Scope.
THE WITNESS: So that the manufacturers would not be surprised when we said -- we suggested that they did not know their customers.
BY MR. ELSNER:
Q. Sorry. Go ahead.
A. No.
Q. Okay. And that's one of the requirements under the Controlled Substances Act, right? In any event, for manufacturers to know their customers?
MR. O'CONNOR: Objection. Form. Scope.
MR. CHANDLER: Objection. Scope.
THE WITNESS: It is part of the regulatory framework.

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BY MR. ELSNER:
Q. In response to this proposed rulemaking, the DEA also received comments.
MR. ELSNER: I will mark this as an exhibit.
(Deposition Exhibit 18 was marked for identification.)
BY MR. ELSNER:
Q. One of the comments was from the PHRMA which is on the third page.
Do you see that?
MS. NEWMARK: I will object to the use of this document as violating the protective order in this case and I repeat all my prior objections.
THE WITNESS: Yes.
BY MR. ELSNER:
Q. And on the second page of that letter, it reads "under diversion and legitimate medical need."
"We're concerned that the DEA seems to conflate legitimate need for opioid treatment with legitimate use of opioids."
Do you see that?
A. Yes.

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Q. And then further down, it reads -- the sentence beginning: "However, illegitimate use of diverted controlled substances."
Do you see that?
A. No. Hold on a sec.
Q. Take your time.
A. Yes.
Q. It says: "However, illegitimate use of diverted controlled substances does not extinguish legitimate need for a drug. For example, if someone steals a pain patient's legally prescribed opioid, the pain patient still has a legitimate need for opioid, even though some of the opioids were diverted for illegitimate uses."
Did I read that correctly?
A. Yes.
Q. And so what is being argued here is that -- that diversion does not affect need; is that a fair summary?
MR. O'CONNOR: Object to form.
MR. CHANDLER: Objection.
MS. McCLURE: Object to form.
MR. EPPICH: Object to form. Mischaracterization of the document.

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THE WITNESS: So that piece suggests that those are two separate factors that should be considered.
BY MR. ELSNER:
Q. And so even in 2018, there were still objections being raised by pain management groups and others to the reminders from the DEA to manufacturers to know their customers and provide that data to the DEA, correct?
MR. O'CONNOR: Objection. Form. Scope.
MR. CHANDLER: Objection. Form. Scope.
THE WITNESS: I don't understand the question.
BY MR. ELSNER:
Q. Even in 2018, as late as that, there were still objections by pain management groups and others to the DEA's proposed rulemaking adding diversion as one of the criteria to consider, correct?
MR. CHANDLER: I'm going to renew my objection.
MR. O'CONNOR: Objection.

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THE WITNESS: They submitted comments objecting, yes.
BY MR. ELSNER:
Q. And were you aware -- this document was produced to us by Purdue and if you look at the very first page, you can see there is an e-mail from Purdue attaching the letter to the DEA.
Was the DEA aware that Purdue was encouraging letters like this to be written to the DEA?
MR. CHANDLER: Objection. Form. Foundation. Characterization of the document.
MR. O'CONNOR: Objection. Form.
MR. CHANDLER: Scope.
MR. O'CONNOR: Scope and foundation.
THE WITNESS: DEA was not aware.
MR. ELSNER: Go off the record for a minute.
THE VIDEOGRAPHER: We are going off the record. The time is 4:51.
(A short recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 4:55.
You may proceed, Counsel.

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BY MR. ELSNER:
Q. Earlier in the deposition, you were asked a question that -- during the years that you approved the quota numbers, did you feel that they reflected the medical need of the United States?
Do you remember that line of questioning?
A. Yes.
MR. CHANDLER: Objection. Mischaracterizes the prior question.
MR. O'CONNOR: Objection.
BY MR. ELSNER:
Q. And you answered that you believed that when you were approving quota allocations, they were based on legitimate medical need.
Do you remember that testimony?
MR. CHANDLER: Objection. Mischaracterizes prior testimony.
MR. O'CONNOR: Objection.
THE WITNESS: So when I approved quota, it was for a legitimate medical need or scientific or research purposes or export or inventory.
BY MR. ELSNER:

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Q When you approved those quota allocation, you were doing that based on the information that you had available to you and to the office of the DEA, correct?
MR O'CONNOR: Objection Form
THE WITNESS: Yes
BY MR ELSNER:
Q And you did your very best with the information that you had to make that determination; is that true?
MR O'CONNOR: Objection
THE WITNESS: Yes
MR ELSNER: I will pass the witness at this time Go off the record
THE VIDEOGRAPHER: We are going off the record This is the end of Media Unit No 5 The time is 4:56
(A short recess was taken)
THE VIDEOGRAPHER: We are going back on the record This is the beginning of Media Unit No 6 The time is 5:23
You may proceed, Counsel
FURTHER EXAMINATION BY COUNSEL FOR DEFENDANTS
BY MR O'CONNOR:
Q Ms Harper-Avilla, hello again

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A. Hello.
Q. I will try to be quick.
Could you turn to Exhibit No. 10, please.
When counsel for plaintiffs asked you some questions about this document, he represented that it was delivered in 2003.
Do you recall that?
A. Yes, that's what he stated.
Q. Where were you in 2003?
A. I was not at DEA.
Q. Did you have any involvement in preparing this presentation?
A. No, I did not.
Q. Do you know who prepared the presentation?
A. No, I do not.
Q. Had you ever seen this presentation before today?
A. Not this one, no.
Q. And can you personally vouch for any of the information contained in this presentation?
MR. ELSNER: Objection.
THE WITNESS: I have not reviewed

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the whole presentation at this point, so no.
BY MR. O'CONNOR:
Q. Do you have any personal knowledge about the statements made in this presentation?
MR. CHANDLER: Object to form.
THE WITNESS: I have not reviewed the entire presentation so I cannot speak to that.
BY MR. O'CONNOR:
Q. Fair to say, you were not involved in making any of the statements in this presentation, correct, because it was delivered in 2003?
A. So I do not know if these are statements that DEA has continued to use since that time, so at the time that this presentation was made, I am not aware of those statements. I have not reviewed the entire presentation.
MR. O'CONNOR: I have no further questions at the moment, but we do reserve the right to leave this deposition open pending the production of the letters from DEA and we are happy to discuss that more offline.
MR. CHANDLER: Okay.

MR. O'CONNOR: Thank you for your time.

THE VIDEOGRAPHER: Does anyone else have any questions? We are off the record at 5:26 p.m., and this concludes today's testimony given by DEA and appearing on their behalf was Stacy Harper-Avilla.

The total number of media units used was six and will be retained by Veritext Legal Solutions.

(Whereupon, the proceeding was concluded at 5:26 p.m.)

CERTIFICATE OF NOTARY PUBLIC

I, Bonnie L. Russo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand and thereafter reduced to computerized transcription under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

Bonnie L Russo

Notary Public in and for
the District of Columbia

My Commission expires: June 30, 2020

Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

April 16, 2019

To: Robert Chandler

Case Name: In Re: National Prescription Opiate Litigation v

Veritext Reference Number: 3282688

Witness: Stacy Harper-Avilla Deposition Date: 4/11/2019

Dear Sir/Madam:

Enclosed please find a deposition transcript Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext com

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3282688
CASE NAME: In Re: National Prescription Opiate Litigation v
DATE OF DEPOSITION: 4/11/2019
WITNESS' NAME: Stacy Harper-Avilla

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me

I have made no changes to the testimony as transcribed by the court reporter

_____ _____
Date Stacy Harper-Avilla

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed

I have affixed my name and official seal

this _____ day of_____, 20____

_____
Notary Public

_____
Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 3282688
CASE NAME: In Re: National Prescription Opiate Litigation v
DATE OF DEPOSITION: 4/11/2019
WITNESS' NAME: Stacy Harper-Avilla

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s)

I request that these changes be entered as part of the record of my testimony

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein

_____ _____
Date Stacy Harper-Avilla

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed

I have affixed my name and official seal this _____ day of_____, 20___

_____
Notary Public

_____
Commission Expiration Date

ERRATA SHEET
VERITEXT LEGAL SOLUTIONS MIDWEST
ASSIGNMENT NO: 3282688

PAGE/LINE(S) / CHANGE /REASON

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_____ _____
Date Stacy Harper-Avilla

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____
DAY OF _____, 20_____ .

_____
Notary Public

_____
Commission Expiration Date

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r

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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